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SNL NWMP QA Procedures Matrix

Revision 7

Effective Date: 11/04/02

Based on the CAO Quality Assurance Program Document Document Number CAO-94-1012

Revision 3

NWMP Matrix

Coordinator: Kathleen Byle Original signed by Kathleen Byle 11-04-02 (printed name) (signature) Date

Note: On-line format of Matrix introduces lines when page breaks occur. See previous or next page for mapping information if page break creates inadvertent empty blocks.

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SNL NWMP QA PROCEDURES MATRIX CAO QAPD (REV. 3), Effective 11/8/99

Section 1 Management Requirements

Sandia National Laboratories ORGANIZATION

QAPD (REV 3) REQUIREMENTS		PPLICA QUIREM DENTIF	IENTS	IMPLEMENTING DOCUMENTS	COMMENTS	
	Υ	N	N/A			
1.1 ORGANIZATION AND QUALITY ASSURANCE PROGRAM	√			NP 1-1		
This section describes the requirement for the organizational structure, primary interfaces, functional responsibilities, and levels of authority required to implement the CAO QA program. In addition, this section describes the basic elements of the QA program and their applicability.						
1.1.1 Organization	√			NP 1-1		Ì
Effective implementation of the CAO QA program is dependent on the efforts at all levels of the program participants. The organization is structured such that the individual performing the work is responsible for achieving and maintaining quality. Management is responsible for defining quality, developing appropriate plans to attain quality, supporting the workers in pursuit of quality, and evaluating quality achievement. QA managers of the program participants are responsible for defining, integrating, and ensuring effective implementation of the CAO QA program. CAO organizational and individual responsibilities are addressed in appendices C and D. Organizational and individual responsibilities for TRU waste characterization and certification activities are addressed in Appendix E.				Sections 2.1, 2.2.1.1 and 2.2.1.4		
1.1.1.1 Management	√			NP 1-1		11
A. Management has overall responsibility for successfully accomplishing activities subject to this QAPD. Management provides the necessary planning, organization, direction, control, resources, and support to achieve their defined objectives. Management is responsible for planning, performing, assessing, and improving the work.				Section 2.2.1.1		
B. Management is responsible for establishing and implementing policies, plans, and procedures that control the quality of work, consistent with the provisions of this QAPD.	√			NP 1-1 Section 2.2.1.1]]

	QAPD (REV 3) REQUIREMENTS		PPLICA QUIREM DENTIF	IENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
C.	Management QA responsibilities include:				NP 1-1	
1.	Ensuring that adequate technical and QA training is provided for personnel performing activities subject to this QAPD				Section 2.2.1.1	
2.	Ensuring compliance with all applicable regulations, DOE orders and requirements, and applicable federal, state, and local laws					
3.	Ensuring that personnel adhere to procedures for the generation, identification, control, and protection of QA records					
4.	Exercising the authority and responsibility to stop unsatisfactory work such that cost and schedule do not override environmental, safety, or health considerations	√			NP 16-1, Section 2.3	
5.	Developing, implementing, and maintaining plans, policies, and procedures that implement this QAPD					
6.	Identifying, investigating, reporting, and correcting quality problems					
D.	Quality achievement is the responsibility of those performing the work. Members of management are responsible for achieving and evaluating quality in their area.	1			NP 1-1 Section 2.2.1.1	
E.	Management empowers employees by delegating authority and decision making to the lowest appropriate level in the organization.	1			NP 1-1 Section 2.2.1.1	
1.1	.1.2 Employees				NP 1-1	
qua exi qua	ch program participant employee is responsible for the ality of his or her work and for promptly reporting all sting, developing, or potential conditions adverse to ality to the responsible management for evaluation and ion.				Sections 2.2.1.1 and 2.2.1.4	
An	.1.3 QA Management organization's QA management has the authority and erall responsibility to independently assess the panization's effective implementation of the QA program.	1			NP 1-1	QAPD Section 1.1.1.3, see NP 1-1 Sections 2.2.1.1 and 2.2.1.3

	QAPD (REV 3) REQUIREMENTS		PPLICA QUIREN DENTIF	IENTS	IMPLEMENTING DOCUMENTS	COMMENTS	
		Υ	N	N/A			
A.	QA management shall	$\sqrt{}$			NP 1-1		
1.	Schedule and conduct QA assessments				Sections 2.2.1.1 and 2.2.1.3		
2.	Maintain liaison with participant QA organizations and other affected organizations						
3.	Ensure preparation, review, and issuance of QA plans and procedures that implement the provisions of this QAPD						
4.	Review and approve supplier and subcontractor QA plans						
5.	Track, perform trend analysis of quality problems, and report quality problem areas						
6.	Provide for the administrative processing of documentation concerning conditions adverse to quality						
7.	Have direct access to responsible management at a level where appropriate action can be effected						
8.	Be sufficiently independent from cost and schedule considerations	√			NP 1-1 Sections 2.2.1.1 and		
9.	Have the organizational freedom to communicate with management				2.2.1.3		
10.	Have no assigned responsibilities unrelated to the quality assurance program that would prevent appropriate attention to QA matters						
11.	Develop, establish, and interpret QA policy and ensure effective implementation						
12.	Interface, as appropriate, with the CAO staff, participants, and other stakeholders on quality assurance matters						
13.	Assist subordinate organizations with quality planning, documentation, quality measurement, and problem identification and resolution						
14.	Provide guidance to all applicable subordinate organizations concerning identification, control, and protection of QA records						
B.	The QA organization shall have sufficient authority, access to work areas, and organizational freedom to	1			NP 1-1 Section 2.2.1.2		
1.	Identify quality problems						
2.	Recommend solutions						
3.	Verify implementation of solutions						
4.	Ensure that unsatisfactory conditions are controlled until proper disposition has occurred						

QAPD (REV 3) REQUIREMENTS		APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS	
	Υ	N	N/A]		
1.1.1.4 Communication and Interface Responsibilities				NP 1-1		
A. Communication Responsibilities				Section 2.2.2		
Participating organizations at all management levels shall establish communication channels that provide timely, and wide dissemination of information pertinent to quality performance, such as						
The status of development and implementation of the QA program						
The status and resolution of significant quality problems						
The lessons learned from significant quality problems and adverse conditions						
Quality management practices and improvements						
5. Trend analysis results						
B. Interface Responsibilities				NP 1-1		1
1. Where more than one organization is involved in the execution of activities covered by this QAPD, the responsibility and authority of each organization shall be clearly established and documented. The external interfaces between organizations, the internal interfaces between organizational units, and interface changes shall be documented. Interface responsibilities shall be defined and documented and shall include the requirements for management, performance, and assessment.	√			Section 2.1		
CAO-sponsored activities, performed by organizations external to the CAO, include, but are not limited to, waste characterization, repository performance assessment, and management and operation of the WIPP facility. Responsible CAO organizations shall ensure the effective implementation of the CAO QA program.	√			SNL NWMP QA Procedures Matrix, Rev. 7	This matrix demonstrates compliance with the CAO QA program.	
1.1.1.5 Delegation of Work				NP 1-1		11
Individuals or organizations responsible for establishing, planning, accomplishing, and assessing the work may delegate work to other individuals or organizations. However, the individuals or organizations making the delegation shall retain overall responsibility for the delegated work.				Section 2.2.1.3		
1.1.1.6 Resolution of Disputes	√			NP 1-1]
Differences of opinion involving the definition and implementation of QA program requirements will be brought to the attention of the appropriate QA manager and the responsible manager. If not resolved, the issues will be elevated progressively to successively higher levels of management as necessary.				Section 2.2.4		

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
1.1.2 Implementation of the CAO QA Program				NP 1-1	
1.1.2.1 Quality Assurance Program Documents				Section 2.2.1.1	
Program participants shall develop and follow plans and procedures that effectively implement the requirements described within this QAPD along with those requirements contained within the RCRA Permit Waste Analysis Plan (WAP), Quality Assurance Project Plans (QAPjPs), Certification QA Plans, Waste Acceptance Criteria (WAC), and TRUPACT-II Certification of Compliance, including TRUPACT-II Authorized Methods for Payload Control (TRAMPAC), as applicable.					
1.1.2.2 Procedures Matrix				NP 5-1	This matrix is
A. Each organization that directly supports CAO activities shall prepare and maintain a procedures matrix that identifies applicable documents of each organization or project that implement each applicable requirement of this QAPD. The matrix shall specifically reference the applicable portion of the procedure or document. The matrix shall be updated as implementation procedures are revised.				Sections 2.1.1 and 2.1.2	maintained on the NWMP on-line documents Web page.
B. When this QAPD is revised, subtier documents such as site QAPjPs, Certification QA Plans, and implementing procedures shall be evaluated and appropriately revised to ensure that the QA program of each organization meets the applicable requirements of the CAO QA program.					
1.1.2.3 Applicability of QAPD Requirements			√	See Comment	This section provides
The QAPD establishes two primary categories of requirements: general requirements and additional requirements. The requirements of QAPD sections that do not identify specific applications are general requirements that shall apply to all items, activities, and processes necessary to ship TRU waste to WIPP. In most cases the general requirements form the introductory portion of a given section, followed by any additional requirements. Several sections of the QAPD have a more limited application, as specifically identified within the given section. The requirements of QAPD sections identified as additional requirements shall apply to all items and activities listed below, unless otherwise specified in this QAPD.					explanatory information. Section 1.1.2.3 of the QAPD provides explanatory information. The N/A for this section indicates that the discussion is not applicable to an implementing document.

	QAPD (REV 3) REQUIREMENTS	REC	PPLICA QUIREM DENTIF	IENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A	200020	
cor cha thro	e terminology "items or activities important to npliance application, nuclear safety, waste tracterization, or waste isolation" is used generically bughout this QAPD to refer to the following:			√	See Comment	
A.	WIPP site activities or operations that process or store radioactive liquid or solid waste; perform waste management activities involving radioactive materials; or design, manufacture, or assemble items for use with radioactive materials in such a form and quantity that a nuclear hazard exists					
B.	Waste characterization activities					
C.	Environmental monitoring, monitoring the performance of the disposal system, sampling and analysis activities					
D.	Field measurements of geological factors, ground water, meteorology, and topography					
E.	Computations, codes, models, and methods used to demonstrate compliance with disposal regulations					
F.	Expert judgement elicitation to support applications for certification or determination of compliance					
G.	Design of the disposal system and actions taken to ensure compliance with design specifications					
H.	The collection of data and information used to support compliance application(s) and/or any modifications to the compliance application					
I.	Other systems, structures, components, and activities important to the isolation of waste in the disposal system					
J.	Those items and activities related to Nuclear Regulatory Commission (NRC) licensed packaging (e.g., Transuranic Package Transporter Model II [TRUPACT-II]): design, purchase, fabrication, handling, shipping, storage, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification or components of packaging which are important to safety					
	2.4 Grading Items and Activities and Applying nagement Controls	√			NP 1-1 Section 1.2	
A.	The graded approach is the process by which the level of analysis, documentation, verification, and other controls necessary to comply with QA program requirements are developed commensurate with the following factors:				SP 1-1, Section 2.1 SP 1-1-1 (Appendix A) NP 4-1, Section 2.1.1	

QAPD (REV 3) REQUIREMENTS		REC	PPLICA QUIREM DENTIF	IENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
1.	The importance of an item or activity with respect to safety, waste isolation, and regulatory compliance.	√			NP 1-1, Section 1.2 SP 1-1	
2.	The importance of the data to be generated					
3.	The need to demonstrate compliance with specific regulatory design and QA requirements					
4.	The impact on the results of performance assessments and engineering analyses					
5.	The magnitude of any hazard or the consequences of failure					
6.	The life-cycle stage of a facility or item					
7.	The programmatic mission of a facility					
8.	The particular characteristics of a facility, item, or activity (e.g., complexity, uniqueness, history, or the necessity for special controls or processes)					
В.	The extent of management and QA controls applied to an item or activity will vary as a function of the degree of confidence needed to achieve the desired quality of the item or activity. The grading process provides the flexibility to design and implement controls that best suit the facility or activity. Each organization should develop their own method to determine that the defined grading process is effective. The use of the graded approach shall determine the appropriate level of controls necessary to manage the items, systems, and activities necessary to ship TRU waste to WIPP.	√			NP1-1, Section 1.2 SP 1-1, Section 2	
C.	Grading methods for each organization shall provide for	√			NP 1-1, Section 1.2 SP 1-1	
1.	The assignment of management and QA control levels					
2.	The definitive criteria used in selecting those levels					
3.	Detailed descriptions of the management and QA control provisions corresponding to those levels, based on the above requirements					
D.	Program participant procedures which establish and implement a graded approach for items and activities under the cognizance of the CAO shall be submitted to the CAO QA Manager for approval for use in CAO programs.	√			NP 1-1, Section 1.2	NP 1-1 was submitted to CAO for review on 1/4/99

QAPD (REV 3) REQUIREMENTS		APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS	
	Υ	N	N/A			
1.1.2.5 Planning Work				NP 20-1		
Planning shall be performed and documented to ensure that work is accomplished under suitably controlled conditions. As appropriate, planning elements shall include:	√			Appendix A		
A. Definition of work scope, objectives, and a listing of the primary tasks involved						
 B. Identification of scientific approaches or technical methods used to collect, analyze, or study results of applicable work 						
C. Identification of field and laboratory testing standards and quality criteria						
D. Identification of applicable implementation documents; appropriate nationally recognized standards shall be used whenever possible						
E. Identification of field and laboratory testing equipment or other equipment						
F. Identification of, or provisions for the identification of, required records and the recording of objective evidence of the results of the work performed						
G. Identification of prerequisites, special controls, specific environmental conditions, processes, or skills						
H. Identification of computer software						
1.1.2.6 Compliance Application Peer Reviews	√			See Comment	CAO Procedure 10.5	
Peer reviews performed in support of WIPP compliance activities shall be documented, as shall all peer review processes. Peer reviews of the following activities shall be conducted in a manner consistent with NUREG-1297, Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories:					is used for peer reviews on the WIPP.	
Conceptual models selected and developed by the DOE						
B. Waste characterization analysis as required in 40 CFR ' 194.24(b)						
C. Engineered barrier evaluation as required in 40 CFR ' 194.44						
1.2 PERSONNEL QUALIFICATION AND TRAINING				NP 2-1		
Personnel shall be trained and qualified to ensure they are capable of performing their assigned tasks and to ensure that job proficiency is maintained.	√					

QAPD (REV 3) REQUIREMENTS	REC	PPLICA QUIREN DENTIF	IENTS	IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
1.2.1 Additional Qualification Requirements Qualification requirements for CAO and participant positions or job functions shall be established for activities important to compliance application, nuclear safety, waste characterization, or waste isolation. The evaluation shall be documented. At a minimum these positions include managers, designers, scientists, independent assessment personnel, operators, maintenance personnel, technicians, and inspectors.	√			NP 2-1 Section 2.1; Appendix A Form NP 2-1-1, Section II, Section III, and Section V.	
A. Analyze each job position to determine the task responsibilities of the position subject to the QAPD. The analysis shall identify minimum education, experience, and training prerequisites for each position involved in the planning, performance, or verification of activities subject to the QAPD, commensurate with the scope, complexity, and nature of the work.	√			NP 2-1 Sections 2.1 and 2.2	
B. Ensure that personnel selected to perform or verify activities subject to the QAPD shall have education, experience, and training commensurate with the minimum requirements specified. The qualification of an individual shall be based upon. evaluation of education and experience, which is compared to the established requirements for the position.					
1.2.2 Additional Training Requirements CAO and participant personnel performing activities important to compliance application, nuclear safety, waste characterization, or waste isolation shall receive related training in accordance with the following requirements. Training shall emphasize the correct performance of work, describe why the applicable quality and nuclear safety requirements exist, and describe the fundamentals of the work and the context. Training shall be subject to ongoing review to determine instruction and training program effectiveness and shall be upgraded whenever needed improvements or enhancements are identified. Management is expected to	√			NP 2-1 Section 2.2	Managers are tasked with responsibility for providing training on technical work performance.
A. Ensure that personnel receive indoctrination and training, including on-the-job and hands-on training, as needed, to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, job responsibilities, and quality assurance implementing procedures, prior to performing any tasks subject to the QAPD	1			NP 2-1 Sections 2.1.2 and 2.2	
B. Ensure that personnel receive indoctrination in the following:	1			NP 2-1 Section 2.2	
 General criteria, including applicable QA plans, codes, regulations, and standards Specific criteria, including applicable QAPjPs and implementing procedures 					QAPjPs are not utilized in SNL work activities.
Ensure that records generated during qualification, general indoctrination and training, or specific skill training activities are collected and maintained as QA records	√			NP 2-1Section 3.0	

QAPD (REV 3) REQUIREMENTS		APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS	
	Υ	N	N/A			
1.3 QUALITY IMPROVEMENT	√			NP 16-1 Sections 1.0, 2.1, and 2.2		
1.3.1 General Requirements						
A. This section defines management responsibility for building a culture in which continuous improvement is a fundamental and integral part of the organization's mission. The program participants shall establish and implement processes to detect and prevent conditions adverse to quality and to ensure continuous improvement. Items and processes that do not meet established requirements shall be identified, controlled, and corrected.				NP 16-1 Section 1.0		
				NP 16-1		
Corrective action for significant conditions adverse to quality shall include identification of the causes of				Sections 2.1, 2.2.2		
adverse conditions and provisions to preclude recurrence. Item reliability, process implementation, and other relevant information shall be reviewed and the data analyzed to identify items and processes needing improvement.				Appendix B		
and the second s				NP 16-1		
C. All personnel shall be responsible for identifying nonconforming items, activities, and processes and shall be encouraged by management to suggest improvements. Management at all levels should foster a "no-fault" attitude to encourage the identification of nonconforming items and processes. Nonconformances shall be documented, evaluated, and dispositioned.				Sections 1.0, 2.2.1		
1.3.2 Additional Requirements	√			NP 16-1		1
The requirements of this section shall apply, in addition to the above requirements, for items, activities, and processes related to compliance application, nuclear safety, waste characterization, or waste isolation.						
1.3.2.1 Identifying and Classifying Conditions	√			NP 16-1	SNL workscope does	1
Adverse To Quality				Sections 2.1 to 2.2.3	not involve "items", therefore	
A condition adverse to quality is an all-inclusive term used in reference to failures, malfunctions, deficiencies, and nonconforming items and processes. Conditions adverse to quality shall be identified and documented. Documentation shall clearly identify and describe the characteristics that do not conform to specified criteria.				Sections 2.1, 2.2.1	"nonconforming items" in this section are not applicable.	
·				NP 16-1		
Conditions adverse to quality shall be classified in regard to their significance. Corrective actions shall be developed accordingly.				Section 2.1		
B. Two categories of classification shall be established:						
Conditions adverse to quality				NP 16-1 Section 2.1		
Significant conditions adverse to quality						

	QAPD (REV 3) REQUIREMENTS		PPLICA QUIREM DENTIF	ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
	Control of Conditions Adverse to Quality Conditions adverse to quality shall be investigated and documented, including the extent of the condition and the impact on completed work. Corrective action plans, as appropriate and as discussed in section 1.3.2.4, shall be developed, documented, and implemented as soon as practical.	√			NP 16-1 Sections 2.2.1, 2.2.2	
В.	reported to and evaluated by the responsible quality assurance organization, other relevant regulatory compliance functions (e.g., environmental and safety), and the responsible management to determine if a work suspension order is necessary. TRU waste sites shall notify CAO of all conditions adverse to quality affecting waste that will be shipped to WIPP. Corrective action plans for significant conditions adverse to quality shall address all provisions of section 1.3.2.4. Management of the responsible organization shall be notified and provided with the results of the subject evaluations.	V			NP 16-1 Sections 2.1 to 2.2.3	
1.	The responsible organization shall issue a work suspension order to the responsible management after a work suspension condition has been identified.	√			NP 16-1 Section 2.3	
2.	The responsible organization shall take appropriate action to lift and close (in part or total) the work suspension order based on the resolution of the related significant condition adverse to quality. The quality assurance organization shall verify and document the completion of applicable corrective actions prior to any management action releasing the work suspension order.					
No of a cor	nconforming items are adverse conditions or the result adverse conditions requiring the following additional ntrols: Nonconforming items shall be identified by marking, tagging, or other methods that do not adversely affect their end use. The identification shall provide traceability to the related adverse condition documentation and shall be legible and easily recognizable. If marking or tagging a nonconforming item is not practical then the item, container, package, or segregated storage area shall be clearly identified. Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. If segregation is impractical or impossible due to physical			√	See Comment	SNL workscope does not involve "items", therefore this section (1.3.2.3) is not applicable.
	conditions, then other administrative controls and precautions shall be employed to preclude inadvertent use of a nonconforming item.					

	QAPD (REV 3) REQUIREMENTS		PPLICA QUIREN DENTIF	IENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
	Nonconforming items shall be controlled to prevent any adverse impact on test, installation, or use. Organizations affected by the nonconformance shall be notified. CAO shall be notified in writing within five (5) calendar days of identification of any nonadministrative nonconformances related to applicable requirements specified in the WIPP Hazardous Waste Permit Waste Analysis Plan (WAP) which are first identified at the Site Project Manager's signature release level (i.e., a failure to meet a Data Quality Objective [DQO]). Notification is also required if the results of the confirmatory analytical techniques specified in the Permit Attachment B are inconsistent with acceptable knowledge documentation. The nonconformance report shall be submitted to CAO within thirty (30) calendar days of identification of the deficiency.			√	See Comment	SNL workscope does not involve "items", therefore this section (1.3.2.3) is not applicable.
D.	Responsibility for the control of further processing, delivery, installation, or operation of nonconforming items, systems, or equipment shall be designated in writing.			$\left \begin{array}{c} \checkmark \\ \end{array}\right $		
	The nonconforming characteristics shall be reviewed, and recommended dispositions of nonconforming items shall be proposed and approved in accordance with documented procedures. The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined in applicable QA plans or implementing procedures. Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.					
F.	The disposition of nonconforming items shall be identified and documented and shall have the concurrence of the quality assurance organization.			√		
1.	The disposition "use as is," "reject," "repair," "rework," or "scrap" for nonconforming items shall be identified and documented. Further processing, delivery, installation, or use of a nonconforming item shall be controlled, in accordance with approved procedures, pending the evaluation and approval of the disposition.					
2.	Items that do not meet original design requirements that are dispositioned "use as is" or "repair" shall be subject to design control measures commensurate with those applied to the original design. The as-built records, if such records are required, shall reflect the accepted deviation. The technical justification for the acceptability of a nonconforming item that has been dispositioned "repair" or "use as is" shall be documented.			√		

	QAPD (REV 3) REQUIREMENTS	REC	PPLICA QUIREN DENTIF	IENTS	IMPLEMENTING DOCUMENTS	COMMENTS
3.	The disposition of an item to be reworked or repaired shall contain a requirement to re-examine (inspect, test, or conduct nondestructive examination) the item to verify acceptability. Repaired or reworked items shall be re-examined using the original process and acceptance criteria unless alternative acceptance criteria or methods have been established and approved as part of the nonconforming item disposition.	Υ	N	N/A √	See Comment	SNL workscope does not involve "items", therefore this section (1.3.2.3) is not applicable.
1.3	.2.4 Corrective Action Planning and Follow-up	1			NP 16-1	
A.	Corrective action plans are required for all significant conditions adverse to quality and for any violation of the WIPP Hazardous Waste Facility Permit and shall address the following points:					
1.	The assessment of the extent and impact of the significant condition adverse to quality (investigative actions)	1			NP 16-1 Section 2.2.2	
2.	The actions to resolve the initial problem (remedial actions)					
3.	The determination of the root cause of the problem					
4.	The actions be taken to preclude recurrence of the problem					
5.	The expected completion dates and responsibilities for the required actions					
B.	A follow-up system shall be established to verify the effective implementation of scheduled corrective actions and to complete the corrective action in a timely manner. The cognizant organization shall evaluate the adequacy of corrective actions planned, assign responsibility for follow-up verification, and perform and document the corrective action verification.	√			NP 16-1 Section 2.2.3 Appendix C	
1.3	.2.5 Improvement Analysis	√			NP 16-1	
A.	Quality performance data shall be identified, collected, and routinely analyzed to identify opportunities to improve items, activities, and processes. This analysis shall consider information from external sources and not be limited to one type of work or to one organization.				Section 2.5	
В.	The analyses shall be performed, in a manner and at a frequency that provides for prompt identification of trends adverse to quality. Reports of conditions adverse to quality shall be evaluated to identify adverse quality trends and identify root causes, with results reported to the organization responsible for corrective action.					
C.	Program participants will report trending information to responsible management and to the applicable quality assurance organization.					

QAPD (REV 3) REQUIREMENTS		PPLICA QUIREM DENTIFI	IENTS	IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
1.3.2.6 Recurring Conditions Adverse to Quality				NP 16-1	
For recurring conditions adverse to quality, management shall, as appropriate				Sections 2.4	
A. Determine the events leading to the occurrences					
Develop an understanding of the technical and work activities associated with the conditions adverse to quality					
C. Ascertain any generic implications					
D. Determine the extent to which similar quality problems, or precursors to the problem, have been recognized by the responsible organization	1			NP 16-1 Sections 2.4	
Determine the effectiveness of any corrective actions that were taken					
F. Identify any generic implications and impacts on completed work					
G. Consider suspending work associated with the applicable activity	√				
Suggest actions that can be taken by the responsible organization to preclude recurrence					
1.4 DOCUMENTS	√			NP 6-1	
1.4.1 General Requirements				Section 1.0 NP 6-2	
Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design.				SP 5-1 Engineering Drawings	
1.4.2 Additional Requirements	√			NP 6-1 Section 1.0	
Documents that specify requirements, prescribe processes, or establish design important to the compliance application, nuclear safety, waste characterization, or waste isolation, such as instructions, procedures, drawings, test plans, management plans, technical reports, performance reports, and test reports, shall be controlled according to the requirements listed below to ensure that correct documents are being employed.					
1.4.2.1 Document Preparation, Review, Approval, and Issuance	√			NP 6-1 Section 2.0	
Documents shall be reviewed for adequacy, correctness, and completeness prior to approval and issuance. Program participants shall identify the individuals or organizations responsible for the preparation, review, approval, and issuance of controlled documents.					
Documents shall be controlled during the review and approval phase in accordance with approved procedures.	√			NP 6-1 Section 2.0	

	QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
B.	The requesting organization shall identify the applicable criteria for the review. These criteria shall consider technical adequacy, accuracy, completeness, and compliance with established requirements.	1			NP 6-1 Section 2.3 and Form NP 6-1-1 Sections 4 & 5	
C.	Pertinent background information or data shall be made available by the organization requesting the review if the information is not readily available to the reviewer.	√			NP 6-1 Section 2.3	
D.	The review will be performed by individuals other than the originator.	√			NP 6-1 Sections 2.2, 2.4, and 2.5	
E.	Reviewers will be technically competent in the subject area being reviewed.					
F.	The organization or technical discipline affected by the document shall review the document according to the established review criteria.					
G.	The appropriate quality assurance organization shall review documents that translate CAO QAPD or WAP requirements.					
H.	Review comment documentation shall be resolved in accordance with approved procedures. Evidence of review comment resolution shall be maintained by the originating organization.					
I.	Documents shall be approved for release by authorities designated in accordance with approved procedures.	 √			NPs 3-1, 5-1, 9-1, 20-1 SP 5-1	
J.	Documents shall be issued by designated individuals or organizations in accordance with approved procedures.	√			NP 6-2 Section 2.0	
1.4	2.2 Document Distribution and Use				NP 6-2	
forr and	e distribution and use of controlled documents and ns that document or prescribe work, including changes l editorial corrections to documents, shall be controlled neet the following requirements:	,			Sections 2.1 to 2.2	
A.	Documents shall be distributed to affected personnel and used at the work location.					
В.	Effective dates shall be established and identified on the approved documents.					
C.	The disposition of obsolete or superseded documents and forms shall be controlled to avoid their inadvertent use.					
D.	Controls shall be established and maintained to identify the current status or revision of controlled documents and forms.					
E.	Controls shall provide for identification of documents to be controlled and their distribution.					

QAPD (REV 3) REQUIREMENTS		APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A	DOCOMENTO	
1.4.2.3 Document Changes Changes to documents, other than those defined below as editorial changes, shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated in accordance with approved procedures.	1			NP 6-1 Section 2.2 NP 6-2 Section 2.1	'Functional areas' is a synonymous term for 'same organization.'
A. Document changes shall be1. Reviewed by the organizations or technical disciplines affected2. Clearly indicated in the changed document	√			1. NP 6-1 Section 2.2 2. NP 6-2 Section 2.1	
 B. Editorial or minor changes may be made without the same level of review and approval as the original or otherwise changed document. The following items are considered editorial or minor changes: 1. Correcting grammar or spelling (the meaning has not changed) 2. Renumbering sections or attachments 3. Updating organizational titles 4. Changes to nonquality affecting schedules 5. Revised or reformatted forms, providing the original intent of the form has not been altered 6. Attachments marked "example," "Sample," or exhibits that are clearly intended to be representative only 7. Clarification changes that don't affect the purpose of the document 	√ 			NP 6-2 Section 2.1 NWMP Glossary under "Editorial Changes"	
 A change in an organizational title accompanied by a change in responsibilities is not considered an editorial change. 	1			NWMP glossary under "Editorial Changes"	
The organization responsible for preparing the document shall identify and approve editorial changes.	√			NP 6-1 Section 2.1 NP 6-2 Section 2.1	
1.5 RECORDS1.5.1 General RequirementsRecords shall be specified, prepared, reviewed, approved, and maintained.	1			NP 17-1 Section 2.1 SP 17-1 Section 1.0	
1.5.2 Additional Requirements A "QA record" is an authenticated record that provides objective evidence of the quality of items or activities. QA records shall be controlled in accordance with the following requirements.	√			NP 17-1 Section 2.1	

	QAPD (REV 3) REQUIREMENTS		APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
1.5	2.1 Records System				NP 17-1	
A.	A QA records system shall be established by the organization responsible at the earliest practical time consistent with the schedule for accomplishing work activities. The QA records system shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation.	√			Section 2.1	
B.	This does not prohibit the management of QA records within a general records system, nor does this require a separate records system for QA records, as long as the applicable provisions of section 1.5.2 are satisfied for the control of QA records.	√			NP 17-1 Section 2.1	
	2.2 Generating QA Records Prior to conducting a work activity, the responsible organization shall	√			NP 17-1 Section 2.1	
1.	Identify those documents that shall become QA records					
2.	Identify the organization responsible for submitting the QA records to the records system					
B.	QA records shall be legible, accurate, and completed appropriate to the work accomplished.	√			NP 17-1 Section 2.1	
C.	Individuals handling documents intended to become QA records shall provide reasonable protection for the records from damage or loss until the records are submitted to the records system (this includes documents generated during field operations).	√			NP 17-1 Section 2.3	
D.	Documents shall be considered valid QA records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. If the nature of the record (such as magnetic or optical media) precludes stamping or signing, then other means of authentication by authorized personnel are required. This authentication represents a certification as to the content of the record by those individuals with knowledge of the related facts, whether by direct personal knowledge or through the direct reports of others. The authentication should not be confused with any subsequent reviews of the content.	√			NP 17-1 Sections 2.1, 2.2.1	
E.	Once authenticated, QA records shall be submitted to the records system, as described above, for either permanent or temporary storage. Upon completion of a project or other discrete task or activity, responsible management shall verify that the contents of the applicable QA records package are stored in the records system.	√			NP 17-1 Section 2.2	
F.	QA records may be originals or reproducible copies unless otherwise required.	√			NP 17-1 Section 2.1	
G.	Documents referenced by final reports, except readily available references such as encyclopedias, dictionaries, engineering handbooks, national codes and standards, etc. shall be retrievable from records files. Preparers of such records shall ensure that the documents are entered into the records system.	√			NP 17-1 Section 2.2	

	QAPD (REV 3) REQUIREMENTS	REC	PPLICA QUIREM DENTIFI	IENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
The	2.3 Indexing QA Records e records system shall provide for the indexing of QA ords according to the following requirements:	√			SP 17-1 Section 1.0	
	An individual or organization shall be assigned the responsibility of indexing and maintaining QA records. The indexing system shall include, at a minimum, record retention times and the location of the record within the records system. These and other features of the record system shall facilitate the disposition of scheduled QA records and ensure the retrievability of	√			SP 17-1 2.1.5; Retrieval 2.1.6; Retention	
QA	any QA records entered. 2.4 Classifying QA Records records shall be classified as either "post-closure," etime," or "nonpermanent."	√			NP 17-1 Section 2.1 SP 17-1 Section 2.1.6, 2.2	
A.	Records that fall into one or more of the following categories shall be classified as "post-closure" QA records:	√			SP 17-1 Section 2.1.6, 2.2	
1.	Records assisting prevention of actions that could impair the long-term isolation of the waste				NP 17-1, Section 2.1	
2.	Records preserving information that would prevent inadvertent human intrusion, such as the nature and hazard of the waste and the locations of the geologic repository operations area, the underground facility, boreholes, and shafts, and boundaries of the controlled area					
3.	Records providing information relevant to post-closure monitoring and assessment of performance of the repository system					
4.	Records preserving for future generations information regarding the geologic setting relevant to mitigation of releases of radioactive materials					
5.	Records of significant value after decommissioning and closure of the repository					
B.	Records not falling into the above-listed categories but into one or more of the following categories shall be classified as "lifetime" QA records:	1			NP 17-1 Section 2.1 SP 17-1	
1.	Records used for repository permitting or certification				Section 2.1.6 Section 2.2	
2.	Records used to identify and assess the performance capabilities of those engineered and natural barriers important to waste isolation				GGGGGT Z.Z	
3.	Records of computer programs and mathematical models needed to perform ongoing correlations between performance assessment predictions and actual tests and data analyses					

	QAPD (REV 3) REQUIREMENTS	REC	PPLICA QUIREM DENTIF	ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
4.	Records of significant value in demonstrating the capability for safe operation of or in determining the cause of an accident or a malfunction of an item in the WIPP repository	√			NP 17-1, Section 2.1 SP 17-1, Sections 2.1.6, 2.2	
5.	Records of significant value in maintaining, reworking, repairing, replacing, or modifying WIPP repository systems, components, or structures					
6.	Records that would be needed during decommissioning and closure of the repository					
7.	Records relating to site characterization samples and data	√			NP 17-1, Section 2.1 SP 17-1, Sections 2.1.6,	
8.	Records relating to data used in performance assessment of the WIPP facility				2.2	
9.	Records relating to the mixed transuranic waste form characterization and acceptance of the mixed transuranic waste form					
10.	Records documenting regulatory compliance					
C.	Records that provide objective evidence that the QA program has been properly implemented but do not meet the above criteria shall be classified as "nonpermanent" QA records.			√	NP 17-1, Section 2.1 SP 17-1, Sections 2.1.6, 2.2	All QA Records are "Permanent/Lifetime"
1.5	.2.5 Receiving QA Records				See Below	
rec res be of c tem	ch organization responsible for the receipt of QA ords shall designate the person or organization ponsible for receiving QA records. The designee shall responsible for organizing and implementing a system controls for the receipt of QA records for permanent and apporary storage. At a minimum, the receipt control stem shall include the following:					
A.	Provisions to permit a current and accurate assessment of the status of QA records	√			SP 17-1, Section 2.1.1 and 2.1.7	
B.	A method for identifying the records required to be included in the records system	√			NP 17-1, Section 2.1	
	A method for identifying the records that have been received	√			SP 17-1, Section 2.1.1	
D.	Procedures for the receipt and inspection of incoming records, including verification that the QA records received are in agreement with the transmittal document and that the records are legible	√			SP 17-1, Section 2.1	
E.	Provisions to control and protect the records from damage or loss during the receiving processes	1			SP 17-1, Sections 2.2.1, 2.2.2	
F.	A method for submittal of completed records to the storage facility without unnecessary delay	1			SP 17-1, Section 2.1.7 NP 17-1, Sections 2.1 and 2.2	
Dis	.2.6 Storage, Preservation, Safekeeping, and position of QA Records QA records shall be stored and preserved in predetermined storage facilities in accordance with approved QA implementing procedures that provide a:	1			SP 17-1 Sections 2.1.1, 2.1.5, 2.1.6, 2.1.8, and 2.2 NP 17-1 Section 2.4	The implementing document applies to QAPD Section 1.5.2.6, A 1-5

	QAPD (REV 3) REQUIREMENTS	REC	PPLICA QUIREM DENTIF	ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
	Description of the storage facility	√			SP 17-1, Sections 2.1.1, 2.1.5, 2.1.6, 2.1.8, and 2.2	
2.	Description of the filing and indexing systems that are used				NP 17-1, Section 2.4	
3.	Method for ensuring that a receipt acknowledgment is returned to the sender					
4.	Description of controls governing QA record access, retrieval, and removal					
	Method for filing supplemental information and documenting the authorization for corrections					
B.	adequate protection of records, including special processed records (such as radiographs, photographs, negatives, microfilm, and magnetic media) to preclude damage from moisture, temperature, rodent infestation, excessive light, electromagnetic fields, or stacking, as appropriate for the type of record being stored.	√ 			SP 17-1 Section 2.2.4	
C.	Records that require special processing and control, such as software and related documentation or information on high density media or optical disks or hardware and software required to maintain and access records, shall be controlled to ensure that the records are useable.	√			NP 17-1 Sections 2.2.1, 2.2.2, and 2.2.3 SP 17-1, Section 2.2.4	
D.	Records Classification and Disposition	√			SP 17-1	
1.	Lifetime QA records are required to be retained and preserved in an acceptable condition for the operating life of the WIPP repository (i.e., until termination of the operating permits), or the particular item while it is installed in the repository or is being stored for future use. Lifetime records shall be evaluated for the need to be upgraded to post-closure records prior to their destruction.				Section 2.2	
2.	Waste characterization data and related QA/QC records in the generator/storage site project files for TRU waste to be shipped to the WIPP facility are designated as either lifetime records of non-permanent records as specified in Attachment B of the WIPP Hazardous Waste Permit. Records that are designated as lifetime records shall be maintained for the life of the waste characterization program at a participating generator/storage site plus six years, then offered to CAO for permanent archival of information of these records in the appropriate form, or transferred to the appropriate Federal Records Center (FRC). Waste characterization records designated as non-permanent records shall be maintained for ten years from the date of (record) generation and then dispositioned according to their approved records inventory and disposition schedule (RIDS). If a generator/storage site ceases to operate, records shall be transferred before closeout.			√		

		QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
			Υ	N	N/A		
3.	was long disp	cords relevant to an enforcement action under the PP Hazardous Waste Permit, regardless of signed dispositions, shall be maintained at the TRU ste site until the NMED determines that they are no ger needed for enforcement actions, and then positioned as required.			√		
4.	ma faci faci TR cer acti ma offe	iste characterization data for each TRU mixed ste container transmitted to WIPP shall be intained by CAO for the active life of the WIPP ility plus two years. The active life of the WIPP ility is defined as the period from the initial receipt of U mixed waste at the facility until NMED receives tification of final closure of the facility. After their ive life, records shall be retired to the FRC and intained for 30 years. These records will then be ered to the National Archives.			√		
E.		sign and construction of a single record storage illity shall meet the following criteria: Reinforced concrete, concrete block, masonry, or equal construction			√		SNL does not have a "single" record storage facility. SNL maintains duplicate storage.
	2.	Floor and roof with drainage control (if a floor drain is provided, a check valve, or equal, shall be included)					
	3.	Doors, structure and frames, and hardware shall be designed to comply with the requirements of a minimum 2-hour fire rating					
	4.	Sealant applied over walls as a moisture or condensation barrier					
	5.	Surface sealant on floor providing a hard wear surface to minimize concrete dusting					
	6.	Foundation sealant and provisions for drainage					
	7.	Forced air circulation with filter system					
	8.	Fire protection system					
	9.	Only those penetrations used exclusively for fire protection, communication, lighting, or temperature/humidity control are allowed; all such penetrations shall be sealed or dampened to comply with the minimum 2-hour fire protection rating					
F.	the wh pro loc and	e construction details shall be reviewed to determine adequacy of protection of contents by a person o is competent in the technical field of fire otection and fire extinguishing. If the facility is ated within a building or structure, the environments d construction of that building can provide a portion all of these criteria.			√		SNL does not have a "single" record storage facility. SNL maintains duplicate storage.

	QAPD (REV 3) REQUIREMENTS		PPLICA QUIREN DENTIF	IENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
G.	 The following are acceptable alternatives to the criteria of section E. above, for a single storage facility: Two-hour fire-rated vault meeting the National Fire Protection Association (NFPA) 232-1986, Standards for the Protection of Records or NFPA 232AM-1986 or both 			√		SNL does not have a "single" record storage facility. SNL maintains duplicate storage.
	Two-hour fire-rated Class B file containers meeting the requirements of NFPA 232-1986 or NFPA 232AM-1986 or both					
	3. Two-hour fire-rated file room meeting the requirements of NFPA 232-1986 or NFPA 232AM-1986 or both, with the following additional provisions:			→		SNL does not have a "single" record storage facility. SNL maintains duplicate storage.
	A. Early warning fire detection and automatic fire suppression capability with electronic supervision at a constantly attended central station					
	B. Records storage in fully enclosed metal cabinets					
	C. Adequate access and aisle ways					
	 D. Prohibition in the room of work not directly associated with record storage or retrieval 					
	E. Prohibition in the room of smoking, eating, or drinking					
	F. Two-hour fire-rated dampers or doors in all boundary penetrations					
H.	If storage at dual facilities for each record is provided, the facilities shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. Each facility is not required to satisfy the requirements of either sections E or F above, but shall meet all other records storage requirements prescribed in this QAPD.	√			SP 17-1 Section 2.2	
I.	When temporary storage of records (such as for processing, review, or use) is required by an organization's procedures, the records shall be stored in a 1-hour fire-rated container. The procedures shall specify the maximum allowable time limit for temporary storage. The container shall bear a UL label (or equivalent) certifying 1-hour fire protection, or be certified by a person competent in fire protection.	√			NP 17-1; 2.3 SP 17-1; 2.2.1, 2.2.2	
J.	Access to storage facilities shall be controlled. A list designating personnel who are permitted access to the QA records shall be maintained and posted. Measures shall be established to preclude the entry of unauthorized personnel into the storage area. These measures shall guard against larceny and vandalism.	√			SP 17-1; 2.2.5 and 2.2.6	
K.	Measures shall be taken to provide for replacement, restoration, or substitution of lost or damaged records.	$\sqrt{}$			SP 17-1; 2.1.8	

	QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
L.	QA records shall not be destroyed until the following conditions are met:	√			SP 17-1 Section 2.2	
	The appropriately assigned National Archives and Records Administration (NARA) authorized disposition specifies destruction					
	2. Regulatory requirements are satisfied					
	 Operational status permits the disposal of such records 					
	The related contractual requirements have been satisfied					
1.5	.2.7. Correcting Information in QA Records				NP 17-1 Section 2.4	
A.	Corrections to records will include the initials or signature of the authorized person making the correction and the date the correction was made.					
В.	Corrections to QA records shall be authorized by the originating organization.					
C.	Corrections to QA records should be made with a single line-through and shall not obliterate the prior entry. QA records shall not be corrected with correction fluids or tapes.					

SNL NWMP QA PROCEDURES MATRIX CAO QAPD (REV. 3), Effective 11/8/99

Section 2 Performance Requirements

Sandia National Laboratories ORGANIZATION

	QAPD (REV 3) REQUIREMENTS		PPLICA QUIREM DENTIFI	ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
2.1 A.	WORK PROCESSES Work shall be performed in accordance with established technical standards and administrative controls. Work shall be performed under controlled conditions using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained.	√			NPs 3-1, 9-1, 20-1, NP 5-1, and 6-2 ("Items" are not applicable to SNL scope of work.) NP 12-1	Design work activities shall be performed IAW Design Plans (3-1), data collection work IAW Test Plans (20-1), and analysis work IAW Analysis Plans (9-1). NP 5-1 governs QA implementing procedures. NP 6-2 governs issuance of approved plans and procedures. NP 12-1 governs calibration and maintenance.
B.	The intent of this section is to establish the policy that each person who performs work is responsible for the quality of his or her work, and he or she will have the goal of doing work correctly the first time. To ensure that the person doing the work achieves that goal, management is responsible for establishing processes and procedures to ensure that all work is planned and performed under controlled conditions by personnel who are knowledgeable of the work requirements, and that these individuals are capable of accomplishing the work in accordance with the requirements of this QAPD.	V			NP 1-1 Sections 2.2.1.4 and 2.2.1.1	
	This section further establishes management involvement in the work processes through their interactions with personnel performing the work and through their review and verification of ongoing and completed work. This will help ensure that the definition of "acceptable work performance" is clearly communicated and that personnel are provided the necessary training, resources, and administrative controls to properly accomplish their tasks.	√			NP 1-1 Section 2.2.1.1	
2.1. A.	Personnel performing work are responsible for the quality of their work. Because the individual worker is the first line in ensuring quality, personnel will be knowledgeable of requirements for work they perform and the capability of the tools and processes they use.	√			NP 1-1 Section 2.2.1.4	
В.	Line managers will ensure that personnel working under their supervision are qualified and are provided the necessary training, resources, and administrative controls to accomplish assigned tasks. Criteria describing acceptable work performance shall be defined for the worker.	√			NP 1-1 Section 2.2.1.1	

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
C. Line managers will review work and related information to ensure that the desired quality is being achieved and to identify areas needing improvement.	√			NP 1-1 Section 2.2.1.1	
D. Work shall be planned, authorized, and accomplished under controlled conditions using technical standards, QA requirements, and implementing procedures commensurate with applicable control levels.	√			NP 1-1 Section 2.2.1.1	
Implementing Procedures A. Implementing procedures shall be developed, reviewed, and approved by technically competent personnel.	√			NP 1-1 NP 5-1 Section 2.3	
 B. Implementing procedures shall include the following information as appropriate to the work to be performed: 1. Responsibilities of the organizations affected by the document 2. Technical, regulatory, quality assurance, or other program requirements 3. Sequential description of the work to be performed, including any allowance for out-of-sequence processing 4. Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished 	√			NP 5-1 Appendix A	
 Prerequisites, limits, precautions, process parameters, and environmental conditions Special qualification and training requirements Verification points and hold points Methods for demonstrating that the work was performed as required (such as provisions for recording inspection and test results, check-off lists, or sign-off blocks) Identification and classification of QA records to be generated by the implementing procedure 					
C. Individuals performing work shall comply with implementing procedures; however, when work cannot be accomplished as described in the implementing procedure or accomplishment of such work would result in an undesirable situation, a condition adverse to quality, or an unacceptable safety risk, the work shall be suspended until the appropriate procedure change provisions are implemented.	√			NP 5-1 Section 2.6	
Item Identification and Control A. Processes shall be established and maintained to identify, control, and maintain items. The identification of items shall be maintained to ensure appropriate traceability. Traceability requirements shall be specified in design documents or implementing procedures. Processes shall be established and implemented to control consumables and items with limited operating or shelf life and to prevent the use of incorrect or defective items.			√	See Comment	SNL work scope does not include "items"; sample identification and control is covered by NP 13-1, M&TE is covered by NP 12-1. Therefore, this section is not applicable. N/A applies to all of Section 2.1.3

	QAPD (REV 3) REQUIREMENTS	REC	PPLICA QUIREN DENTIF	MENTS	IMPLEMENTING DOCUMENTS	COMMENTS	
		Υ	N	N/A			
B.	The following additional controls shall be established to ensure that only correct and accepted items are used or installed: Items shall be identified and traced from the time of receipt, up to and including installation or end use. Records shall be maintained to ensure that the item can be traced at all times from its source through installation or end use.			√			
2.	Item identification methods shall include physical markings. If physical markings are either impractical or insufficient, other appropriate means shall be employed (such as physical separation, labels or tags attached to containers, or procedural control). When used, physical markings shall a. Be applied using materials and methods that provide a clear, permanent, and legible identification b. Not be detrimental to the function or service life of the item c. Be transferred to each part of an identified item when the item is subdivided d. Not be obliterated or hidden by surface treatments, coatings, or installation unless other			√			
3.	means of identification are substituted If codes, standards, or specifications include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification or grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records), then identification and traceability methods shall be implemented to ensure meeting the special requirements.			√			
4.	Item identification control system records shall provide the inspection, test, and operating status of items. Items that have satisfactorily passed the required inspections and tests shall be identified. The identification methods shall preclude the inadvertent installation, use, or operation of items that have not passed required inspections and tests.			√			
5.	The status of inspections and tests shall be identified either on the items or in documents traceable to the items. Status shall be maintained through the use of status indicators (such as tags, markings, labels, and stamps) or other means (such as inspection or test records), and the authority for applying and removing status indicators shall be specified.			√			
2.1 A.	.4 Special Processes Processes shall be considered as special processes if they meet any one or combination of the following criteria:			√	See Comment	SNL work scope does not involve "Special Processes," therefore this section is not applicable.	

QAPD (REV 3) REQUIREMENTS		PPLICA QUIREN DENTIF	IENTS	IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A	DOOOMEITTO	
 The results are highly dependent on the control of the process The results are highly dependent on the skill of the operator The quality of the results cannot be readily determined by inspection or test of the product 					
B. Implementing procedures shall be developed and implemented to ensure that special process parameters are controlled and specified environmental conditions are maintained. In addition to the requirements provided in section 2.1.2, special process implementing procedures shall include or reference			√		See Comment to QAPD Section 2.1.5
 The requirements for training/qualification of personnel and quality processes/equipment The conditions necessary for completion of the special process, including equipment, statistical process control, controlled parameters of the process, and calibration requirements 					
2.1.5 Handling, Storage, and Shipping					SNL work scope does not include "items";
A. Handling, storage, cleaning, shipping, and other means of preserving, transporting, and packaging of items shall be conducted in accordance with established work and inspection procedures, shipping instructions, or other specified documents.			√		sample identification and control is covered by NP 13-1, M&TE is covered by NP 12-1. Therefore, this section is not applicable.
B. If required for critical, sensitive, perishable, or high-value articles, specific implementing procedures for handling, storage, cleaning, packaging, shipping, and other preservation shall be prepared and used.			√		See Comment to QAPD Section 2.1.5
C. Measures shall be established and implemented for the marking and labeling of items for packaging, shipping, handling, and storage as necessary to adequately identify, maintain, and preserve the item. Markings and labels shall indicate the presence of special environments or the need for special controls, as necessary, and be applied and removed by authorized personnel.			√		See Comment to QAPD Section 2.1.5
D. If required for protection or maintenance of particular items, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas and specific moisture and temperature levels) shall be specified, planned for, and provided.			√		See Comment to QAPD Section 2.1.5
 If special protective equipment and environments are used, provisions shall be made for verifying their adequacy. Special handling tools and equipment shall be used and controlled, as necessary, to ensure safe and adequate handling. 					

	QAPD (REV 3) REQUIREMENTS	REC	PLICA UIREM ENTIFI	ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A	DOCOMENTO	
	 Special handling tools and equipment shall be inspected and tested at specified intervals and in accordance with implementing procedures to verify that the tools and equipment are adequately maintained. Operators of special handling and lifting equipment shall be sufficiently experienced and trained to use the equipment. 					
E.	If storage of items is required, then methods shall be established for the control of item identification records that are commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable: 1. Maintenance or replacement of markings and identification tags damaged during handling or aging 2. Protection of identification markings that are subject to excessive deterioration resulting from environmental exposure 3. Update of related identification records and			√		See Comment to QAPD Section 2.1.5
F.	documentation Status indicators, such as tagging valves and switches to prevent inadvertent operation, shall be used to indicate the operating status of items. Status indicators, such as lockout tagging, shall also be used where appropriate and shall be applied and removed by authorized personnel.			√		See Comment to QAPD Section 2.1.5
2.2	-					
2.2 Ite en sta incode be protent an	ns and processes shall be designed using sound gineering and scientific principles and appropriate ndards. Design work, including changes, shall orporate appropriate requirements such as general sign criteria and design bases. Design interfaces shall identified and controlled. The adequacy of design ducts shall be verified by individuals or groups other in those who performed the work. Required verification divalidation work shall be completed before approval dimplementation of the design.	√			NP 3-1	
(fro	s section provides requirements to ensure that designs on conceptual through final) are defined, controlled, and ified. In establishing design controls, management is ponsible for ensuring that design inputs are technically rect; that design interfaces are identified; that horities, responsibilities, and lines of communication are arly defined; and that the design processes clearly line the acceptance criteria for the product.	√			NP 3-1	

	QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
App des req tho	c.2.1 Design Input plicable design inputs such as design bases, conceptual sign reports, performance requirements, regulatory uirements, codes, and standards shall be controlled by se responsible for the design in accordance with the owing requirements:	√			NP 3-1 Appendix A	
A.	Design inputs shall be identified and documented and their selection reviewed and approved by those responsible for the design.					
B.	Design inputs shall be specified and approved on a timely basis and to the level of detail necessary to permit the design work to be carried out correctly in a manner that provides a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes.	√			NP 3-1 Appendix A	
C.	<u> </u>	√			NP 3-1 Appendix B	
D.	Design inputs based on assumptions that require reverification shall be identified and controlled.	√			NP 3-1 Section 2.4	
2.2	.2.2 Design Process					
follo	e design process shall be controlled according to the owing requirements: Appropriate standards shall be identified and	√			NP 3-1 Appendices	
Α.	documented and their selection reviewed and approved. Changes from specified standards, including the reasons for the change, shall be identified, approved, documented, and controlled.				A and B	
B.	Design work shall be prescribed and documented on a timely basis and to the level of detail necessary to permit the design process to be carried out correctly.					
C.	Design documents shall be adequate to support design, fabrication, construction, and operation.		•			
D.	Design documents shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can understand the documents and verify their adequacy without recourse to the originator.					
E.	Controls for identifying assemblies or components that are part of the item being designed shall be established. If a commercial grade assembly or component is modified or selected by special inspection or testing to meet requirements that are more restrictive than the supplier's published product description, then the assembly or component shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.					
F.	Controls for selecting and reviewing design methods, materials, parts, equipment, and processes essential to the function of an item shall be established.					

QAPD (REV 3) REQUIREMENTS		REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A	20002	
G.	Drawings, specifications, and other design output documents shall contain appropriate inspection and testing acceptance criteria.					
2.2	2.3 Design Analyses				NP 3-1	
A.	Design analyses shall be planned, controlled, and documented.	√			Section 2.2	
B.	Documentation of design analyses shall include				NP 3-1	NP 3-1 notation applies
	1 Definition of the chicative of the analyses				Section 2.2	to 2.2.2.3 B
	 Definition of the objective of the analyses Definition of design inputs and their sources Results of literature searches or other applicable background data 	√			Appendix A and B	
	 4. Identification of assumptions and designation of those assumptions that shall be verified as the design proceeds 5. Identification of any computer calculations, including computer type, computer software name, revision identification, inputs, outputs, and the bases (or reference thereto) supporting application of the software to the specific physical problem 6. Identification of the reviewer and the approver 	√			NP 3-1 Section 2.2 Appendix A and B	
C.	Calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date, or by other designator such that the calculations are traceable.	√			NP 3-1 Section 2.2	
D.	Computer software used to perform design analyses shall be developed, qualified, and used according to the requirements of section 6.	√			NP 3-1 Section 2.2	
2.2	2.4 Design Interface					
	sign interfaces shall be identified and controlled so that orts are coordinated among participating organizations.	√			NP 3-1 Appendix A	
A.	Design interface controls shall include the assignment of responsibility and the establishment of implementing procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.					
В.	Design information transmitted across interfaces shall be documented and controlled.					
	The status of the design information or issued design documents shall be identified in transmittals. Where necessary, incomplete designs that require further evaluation, review, or approval shall be identified.					
2.2	2.5 Design Verification					
des ver	e acceptability of design work and documents, including ign inputs, processes, outputs, and changes, shall be fied. The following design control requirements shall applied to verify the adequacy of design:	√			NP 3-1 Section 2.3	

QAPD (REV 3) REQUIREMENTS		APPLICABLE REQUIREMENTS IDENTIFIED			IMPLEMENTING DOCUMENTS	COMMENTS	
		Υ	N	N/A			
A.	Design verification shall be performed using one or a combination of the following methods: 1. Design review 2. Alternate calculations 3. Qualification testing	√			NP 3-1 Section 2.3	SNL does not use qualification testing on NWMP design activities.	
B.	The particular design verification method shall be identified and its use justified.	√			NP 3-1 Section 2.3		1
C.	The results of design verification shall be documented, including the identification of the verifier.	1			NP 3-1 Section 2.3]
D.	Design verification shall be performed by competent individuals or groups other than those who performed the original design (but they may be from the same organization). If necessary, this design verification may be performed by the originator's supervisor provided that	1			NP 3-1 Section 2.3 Part C	SNL QA Program does NOT allow supervisors to perform design verification.	_
	 The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design The supervisor is the only individual in the organization competent to perform the verification The determination to use the supervisor is documented and approved in advance 			√		SNL QA Program does not allow supervisors to perform verification.	_
E.	Design verification shall be performed at appropriate times during the design process. 1. Verification shall be performed before release for procurement, manufacture, construction, or release to another organization for use in other design work. 2. Design verification shall be completed before relying on the item to perform its function.	√			NP 3-1 Section 2.3		
F.	The extent of the design verification required shall be based on the complexity, risk, uniqueness of the design, complexity of design, degree of standardization, state of the art, and similarity with previously proven designs. When the design has been subjected to a verification process in accordance with this QAPD, the verification process need not be duplicated for identical designs.	√			NP 3-1 Section 2.1.2		
G.	Use of previously proven designs shall be controlled according to the following requirements: 1. The applicability of standardized or previously proven designs shall be verified with respect to meeting pertinent design inputs for each application. 2. Known problems affecting standard or previously proven designs and their effects on other features shall be considered.	1			NP 3-1 Section 2.3 Part D		

QAPD (REV 3) REQUIREMENTS	REC	PPLICA QUIREN DENTIF	IENTS	IMPLEMENTING DOCUMENTS	COMMENTS	
	Υ	N	N/A	DOOGWILITIO		
 The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design. Changes in previously verified designs shall require reverification. Such reverifications shall include the evaluation of the effects of those changes on the overall previously verified design and on any design analyses upon which the design is based. 						
Design Reviews Design reviews shall be controlled, documented, and performed. Design reviews shall consider the following:	√			NP 3-1 Appendix C		
Design inputs were correctly selected and incorporated.						
 Assumptions necessary to perform the design work were adequately described, reasonable, and reverified as necessary. Appropriate design methods were used. Design output is reasonable compared to design inputs. The necessary design input and verification requirements for interfacing organizations were specified in the design documents or in supporting implementing procedures. 	√			NP 3-1 Appendix C		
B. Disposition of design review comments shall be documented.	1			NP 3-1 Appendix C		
2.2.2.7 Alternative Calculations These are calculations or analyses that are made using alternate methods to verify correctness of the original calculations or analyses. The appropriateness of any assumptions, the input data used, any computer programs, or other calculation methods used shall be evaluated.	√			NP 3-1 Appendix C		
2.2.2.8 Qualification Testing If design adequacy is to be verified by qualification tests, the tests shall be pre-identified. When qualification testing is used, the following requirements shall apply: A. The test configuration shall be defined and			√	See Comment	SNL does not use this form of testing on NWMP design activities.	
documented. B. Testing shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item shall perform satisfactorily shall be considered in determining the most adverse conditions.						
C. If the tests verify only specific design features, then the other features of the design shall be verified by other means.						

	QAPD (REV 3) REQUIREMENTS		PLICA	IENTS	IMPLEMENTING	COMMENTS
		Y	N N	N/A	DOCUMENTS	
D.	Test results shall be documented and evaluated by the responsible design organization to ensure that test requirements have been met.					
E.	If qualification testing indicates that a modification to an item is necessary to obtain acceptable performance, then the modification shall be documented and the modified item retested or otherwise verified to ensure satisfactory performance.					
F.	Scaling laws shall be established and verified when tests are being performed on models or mockups.					
	The results of model test work shall be subject to error analysis, where applicable, before using the results in final design work.					
2.2	.2.9 Design Change					
	sign changes shall be controlled in accordance with the owing requirements:				NP 3-1 Section 2.5	
A.	Changes to final designs, field changes, and nonconforming items dispositioned "use as is" or "repair" shall be justified and shall be subject to design control measures commensurate with those applied to the original design.	√				
B.	Design control measures for changes shall include provisions to ensure that the design analyses for the item are still valid.	√			NP 3-1 Section 2.5	
C.	Changes shall be approved by the same groups or organizations that reviewed and approved the original design documents.	√			NP 3-1 Section 2.5	
	 If an organization that originally was responsible for approving a particular design document is no longer responsible, then a new responsible organization shall be designated. The cognizant design organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design. 					
D.	If a significant design change becomes necessary because of an incorrect original design, the design process and design verification methods and implementing procedures shall be reviewed and modified as appropriate. These design deficiencies shall be documented according to the requirements provided in section 1.3.2.	√			NP 3-1 Section 2.5	
E.	Field changes shall be incorporated into the applicable design documents.	√			NP 3-1 Section 2.5	
F.	Design changes that affect related implementing procedures or training programs shall be communicated to the appropriate organizations.	√			NP 3-1	
	communicated to the appropriate organizations.				Section 2.5	

QAPD (REV 3) REQUIREMENTS	REC	PPLICAI QUIREM DENTIFI	ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
2.3 PROCUREMENT 2.3.1 General Requirements CAO and participant organizations shall ensure that participant organizations comply with applicable Federal Acquisition Regulations (FARs) that procured items and services meet established technical and QA requirements, and that they perform as specified. Prospective suppliers shall be evaluated and selected on the basis of documented criteria. The responsible organization shall verify that approved suppliers continue to provide acceptable items and services.	√			NP 4-1: Sections 2.1.1, 2.1.2, 2.1.3, 2.4, 2.5, and 2.6	The FAR is implemented based on a combination of DOE and SNL corporate guidance.
2.3.2 Additional Requirements					
The procurement of items and services shall be controlled in accordance with the requirements of the following sections.	√			See Below	
2.3.2.1 Procurement Planning Requirements Procurement activities shall be planned as early as possible and documented to ensure a systematic approach to the procurement process. Procurement planning shall A. Identify procurement methods and organizational responsibilities, including the appropriate QA organization	√			NP 4-1	Evidence of the planning of procurement activities is provided by the existence of NP 4-1, itself, and the SNL corporate-level Purchasing Instructions that are not subject to this QAPD.
 B. Identify and document the sequence of actions and milestones needed to effectively complete the procurement. Provide for the integration of the following activities: 1. Procurement document preparation, review, and change control 2. Selection of procurement sources 3. Proposal or bid evaluation and award 4. Purchaser evaluation of supplier performance 5. Purchaser verifications including any hold-point and witness-point notifications 6. Control of nonconformances 7. Corrective action 8. Acceptance of the item or service 9. Identification of QA records 	√			NP 4-1: Appendix B, Section 2.0 (for 1-6), Section 2.5.3 (for 7), Section 2.5 and 2.6 (for 8) and Section 3.0 (for 9).	
Supplier Selection Supplier selection shall be based on an evaluation of the supplier's capability to provide items or services in accordance with procurement document requirements. Organizations responsible for supplier source selection shall be identified and shall include the appropriate QA organization.	√			NP 4-1: Section 2.1.3, Section 2.4, Section 2.5, and Section 2.6	

QAPD (REV 3) REQUIREMENTS	REC	PPLICA QUIREM DENTIFI	ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
B. Measures for selecting procurement sources shall include one or more of the following elements: 1. An evaluation of the supplier's history for providing an identical or similar product that performs satisfactorily in actual use 2. An evaluation of the supplier's current QA documentation supported by any documented qualitative and quantitative information 3. An evaluation of the supplier's technical and QA capability based on an evaluation of the supplier's facilities, personnel, and quality program implementation	✓			NP 4-1: Section 2.1.3, Section 2.4, Section 2.5, and Section 2.6	
C. The results of procurement source selection shall be documented.	√			NP 4-1: Section 2.2, Section 2.4, Section 2.5, and Section 2.6	
2.3.2.3 Proposal/Bid Evaluation					
A. The proposal or bid evaluation process shall include a determination of the extent of conformance to the procurement document requirements. This evaluation shall be performed by designated, technically qualified personnel, including the quality assurance organization, and shall include, at a minimum, the following:	√			NP 4-1: Section 2.1.1, Section 2.2, Section 2.4, Section 2.5, Section 2.6, and Appendix A	
 Technical considerations QA program requirements 					
 Supplier personnel skills Supplier production capabilities Supplier past performance Alternatives proposed by the supplier Exceptions taken by the supplier 					
B. Before the contract is awarded, the purchaser shall resolve, or obtain commitments to resolve, deficiencies identified during the proposal or bid evaluation.	√			NP 4-1: Appendix A, "Bid Award Open Items" portion	
C. Supplier QA provisions shall be accepted by the purchaser QA management before authorizing the supplier to start work.	√			NP 4-1: Section 2.1.3	
2.3.2.4 Procurement Document Requirements					
Procurement documents shall include the following, as applicable to the item or service being procured:	√			NP 4-1: Section 2.1.1, Section 2.1.3	
A. The scope of work					

	QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
B.	Technical requirements, including the following: 1. Design bases shall be identified or referenced. 2. Specific documents (such as drawings, codes, standards, regulations, DOE orders, procedures, or instructions) that describe the technical requirements of the items or services to be furnished shall be identified. The revision level or change status of these documents shall also be identified 3. Tests, inspections, hold points or acceptance criteria that the purchaser shall use to monitor and evaluate the performance of the supplier shall be specified.	√			NP 4-1: Section 2.1.1, Section 2.1.3	
C.	 QA provisions specified by the purchaser QA organization shall include The requisite QA and documentation requirements, depending on the control level of the item or service being procured The pass-down requirements that the supplier shall incorporate into any sub-tier procurement document When deemed appropriate, the purchaser may permit some or all supplier work to be performed under the purchaser QA program, provided that the requirements are adequately implemented. In these cases, procurement documents shall specify that the purchaser's QA implementing procedures are applicable to the supplier and that the purchaser shall provide these applicable documents to the supplier. 	√			NP 4-1: Section 2.1.1, Section 2.1.3, both "Procurement Request Documentation" portion and "QA Requirements section" portion and Section 2.6	
D.	Right of access to supplier facilities and records for inspection or audit by the purchaser, CAO, or other designee authorized by the purchaser	1			NP 4-1: Section 2.1.3	
E.	The requirements of section 1.5 and provisions for disposition, if the supplier is required to maintain QA records	√			NP 4-1: Section 2.1.3	Suppliers are required to adhere to either the QAPD (incl. QA records requirements) or SNL NP 17-1. All suppliers are required to forward QA records to SNL for disposition.
F.	Requirements for the supplier to report nonconformances and obtain purchaser approval of supplier recommended dispositions	√			NP 4-1: Section 2.4, Section 2.5, and Section 2.6	
G.	Spare and replacement parts or assemblies and the appropriate technical and QA requirements for ordering	1			NP 4-1: Section 2.4, Section 2.5, and Section 2.6	
H.	Requirements for the use, control, and calibration of measuring and test equipment in conformance to the requirements of ANSI/NCSL Z540-1, Calibration Laboratories and Measuring and Testing Equipment – General Requirements	√			NP 4-1: Section 2.1.3	Suppliers are required to adhere to either the QAPD (incl. M&TE control requirements) or SNL NP 12-1, which includes this rqmt.

QAPD (REV 3) REQUIREMENTS		PPLICA QUIREN DENTIF	IENTS	IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A	2000	
2.3.2.5 Procurement Document Review and Approval					
A. A review of the procurement documents and any changes thereto shall be made to verify that documents include appropriate provisions to ensure that items or services shall meet the prescribed requirements.	√			NP 4-1: Section 2.1.4 and 2.1.5	
Procurement document reviews shall be performed and documented prior to the document being issued to the supplier.	√			NP 4-1: Section 2.1.4 and 2.1.5	
C. Reviews shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and scope of the procurement.	√			NP 4-1: Section 2.1.4 and 2.1.5	
Procurement document reviews shall include representatives from the technical and QA organizations and shall be approved by appropriate management.	√			NP 4-1: Section 2.1.4 and 2.1.5 for technical and QA reviews. Section 2.1.5 for management approval.	
2.3.2.6 Supplier Performance Evaluation Requirements					
The purchaser of items and services shall establish measures to interface with the supplier and to verify supplier performance, as deemed necessary by the purchaser. The measures shall include: A. Establishing an understanding between the purchaser and supplier of the requirements and specifications identified in the procurement documents	√			NP 4-1, in its entirety	Procurement documents and the process of placing a procurement accomplish this.
Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements	√			NP 4-1: Section 2.1.3	
C. Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement requirements	√			NP 6-1	
Identifying and processing necessary change information	√			NP 4-1 Section 2.3	
E. Establishing the method to be used to document information exchanges between purchaser and supplier	√			NP 4-1: Section 2.4 and Section 2.6	
F. Establishing the extent of assessment activities and inspection	√			NP 4-1: Section 2.4 and Section 2.6	
2.3.2.7 Acceptance of Items or Services					
A. Source Verification The purchaser may accept an item or service by monitoring, auditing, surveilling, witnessing, or observing activities performed by the supplier. This method of acceptance is called source verification. The extent of source verifications shall be a function of the relative importance, complexity, and quantity of items or services being procured as well as the supplier's quality of performance. Source verifications shall be accomplished as early as possible, but prior to the start of those activities that are required to be controlled, and shall include the	√			NP 4-1: Section 2.4	
that are required to be controlled, and shall include the active involvement of the purchaser's QA organization. In addition:					

QAPD (REV 3) REQUIREMENTS	REC	PPLICA QUIREM DENTIF	ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
Source verification shall be accomplished consistent with the supplier's planned inspections, examinations, or tests and performed at intervals consistent with the importance and complexity of the item. Documented evidence of acceptance of source verified items or services shall be furnished to the party receiving the item, to the purchaser, and to the supplier. Source verification shall be performed by qualified	Y √	N	N/A	NP 4-1: Section 2.4	
personnel. B. Receiving Inspection	,				
When a receiving inspection is used to accept an item 1. The inspection shall include consideration of source assessments, verifications, and audits and the demonstrated quality performance of the supplier.	√			NP 4-1: Section 2.4, Section 2.5, Section 2.6, and SP 1-1, Appendix A (Form SP 1-1-1)	
The inspection shall be performed in accordance with established inspection procedures or instructions.					
 The inspection shall verify, as applicable, proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness. The inspection shall be planned and executed in accordance with the applicable requirements of section 2.4. Receiving inspection shall include a review of the adequacy and completeness of any required supplier documentation. 					
C. Post-Installation Testing					
When post-installation testing is used as a method of acceptance, then post-installation test requirements and acceptance documentation shall be mutually established and agreed upon by the purchaser and supplier.	√			NP 4-1	
D. Supplier Certificate of Conformance When a certificate of conformance is used, the following, at a minimum, shall be met: 1. The certificate shall identify the purchased material or equipment, including the purchase order and item number or other identification that is traceable to the requirements of the procurement document	√			NP 4-1	
The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.	√			NP 4-1	

QAPD (REV 3) REQUIREMENTS	APPLICA REQUIREM IDENTIF		IENTS	IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A	BOOMENTO	
The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances.	√			NP 4-1	
 The certificate shall be signed or otherwise authenticated by an official of the supplier organization. 	√			NP 4-1	
 The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the purchaser or supplier QA program. 	√			NP 4-1	
6. Means shall be provided to verify the validity of supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the supplier or independent inspection or test of the items. Such verification shall be conducted by the purchaser at intervals commensurate with supplier quality performance.	√			NP 4-1	
2.3.2.8 Control of Supplier Nonconformances The purchaser and supplier shall establish and document the process for dispositioning items that do not meet procurement document requirements in accordance with the following:			√		Items outside the scope of SNL QA Program.
A. The supplier shall submit a report of nonconformance to the purchaser that includes supplier-recommended disposition (for example, "use as is" or "repair") and provide technical justification for such disposition.					
B. Reports of nonconformances to procurement document requirements or documents approved by the purchaser shall be submitted to the purchaser for approval. Examples of conditions requiring a report of nonconformance include:			√		Items outside the scope of SNL QA Program.
 Failure to meet technical or material requirements Failure to meet a requirement in supplier documents that have been approved by the purchaser 					
The nonconformance cannot be corrected by continuation of the original manufacturing process or by rework					
The item does not conform to the original requirement even though the item can be restored to a condition such that the item's capability to function is unimpaired					
C. The purchaser shall evaluate the supplier-recommended disposition.			√		Items outside the scope of SNL QA Program.
D. The purchaser shall verify implementation of the disposition.			√		Items outside the scope of SNL QA Program.

QAPD (REV 3) REQUIREMENTS	REC	PPLICA QUIREM DENTIF	ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
2.3.2.9 Commercial Grade Items Where the design specifies the use of commercial grade items, the following requirements are an acceptable alternative to other requirements of this section.	√			NP 4-1	Section 2.3.2.9 implemented in NP 4-1.
A. The commercial grade item shall be identified in an approved design output document, such as drawing, specification, or other document translated from a design input document. An alternative commercial grade item may be applied as long as the responsible design organization provides verification that the alternative commercial grade item performs the intended function and meets design requirements that are applicable to both the replaced item and its application.					
B. Supplier selection shall be in accordance with source selection requirements.					
C. Commercial grade items shall be identified in the procurement document by the manufacturer's published product description.	$\sqrt{}$				
After receipt of a commercial grade item, the purchaser shall ensure that	√				
 Damage was not sustained during shipment The item received was the item ordered Inspection or testing is accomplished, to the extent determined by the purchaser, to ensure conformance with the manufacturer's published requirements Documentation, as applicable to the item, was received and is acceptable 					
2.4 INSPECTION AND TESTING				See Comment	Sections 2.4.1, 2.4.2
2.4.1 General Requirements Inspections and testing shall be performed in accordance with approved implementing procedures. An essential part of the work planning process is to identify the items and processes to be inspected or tested, the parameters or characteristics to be evaluated, the techniques to be used, the acceptance criteria, any hold points, and the organizations responsible for performing the tests and inspections. Inspection for acceptance shall be performed by personnel other than those who performed or directly supervised the work being inspected. Inspection and testing of specified items and processes shall be conducted using established acceptance and performance criteria. The acceptance of items and processes shall be made by and documented by qualified and authorized personnel. Equipment used for inspections and tests shall be calibrated and maintained.			√		and their subsections are not applicable to SNL work.
2.4.2 Additional Requirements Inspection and testing activities shall be conducted in accordance with the following requirements, as applicable.			√		

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
2.4.2.1 Qualification of Inspection and Test Personnel This section provides amplified requirements for the qualification of personnel who perform inspection and testing to verify conformance to specified requirements for the purpose of acceptability. The requirements of this section do not apply to the qualification of personnel for performance of nondestructive examination. Qualification of personnel for nondestructive examination is addressed in section 2.4.2.2.			√		
A. The responsible organization shall designate those activities that require qualified inspection and test personnel and the minimum requirements for such personnel. Further, the responsible organization shall establish written procedures for the qualification of inspection and test personnel and for the assurance that only those personnel who meet the requirements of this section are permitted to perform applicable inspection and test activities.			√		
B. When a single inspection or test requires implementation by a team or a group, personnel not meeting the requirements of this section may be used in data-taking assignments or in plant or equipment operation, provided they are supervised or overseen by a qualified individual.			√		
C. Personnel selected for performing inspection and test activities shall have the experience or training commensurate with the scope, complexity, or special nature of the activities.			√		
D. Provisions shall be made for the indoctrination of personnel to the technical objectives and requirements of the applicable codes and standards and the QA program controls that are to be employed.			√		
E. The need for a formal training program shall be determined, and such training activities shall be conducted as required to qualify personnel that perform such inspections and tests. On-the-job training shall also be included in the program, as appropriate, with emphasis on first-hand experience gained through actual performance of inspections and tests.			√		
F. The capabilities of a candidate for certification shall be initially determined by a suitable evaluation of the candidate's previous education, experience, training, and either test results or capability demonstration.			√		

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
G. The job performance of inspection and test personnel shall be reevaluated for capability at periodic intervals not to exceed three years. Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the above requirements. If during this evaluation, or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. Any person who has not performed inspection or testing activities in their qualified area for a period of one year shall be reevaluated for the required capability in accordance with the above requirements.			√		
H. The qualification of personnel shall be certified in writing in an appropriate form and shall include the following information: 1. Employer's name 2. Identification of person being certified			√		
 Activities certified to perform Basis used for certification, including such factors as: (1) education, experience, indoctrination, and training; (2) test results, where applicable; and (3) results of capability demonstration Results of periodic evaluation Results of physical examinations, when required Signature of employer's designated representative who is responsible for such certification The date of certification and date of certification expiration 					
I. The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination.			√		
J. Records of personnel qualification shall be established and maintained by the employer. These records shall include the information required above for certification.			√		
2.4.2.2 Qualification of Nondestructive Examination Personnel This section identifies the requirements for the qualification					
of personnel who perform nondestructive examination (NDE) (radiographic, magnetic particle, ultrasonic, liquid penetrant, eddy current, neutron radiographic, and leak testing) to verify conformance to specified requirements, for nondestructive examination activities performed at the WIPP site.			√		

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
A. The American Society of Nondestructive Testing (ASNT) Recommended Practice No. SNT-TC-1A, June 1980 Edition, and its applicable supplements shall apply as requirements for personnel performing the above methods of NDE.					
B. The responsible organization shall establish written procedures for the control and administration of the training, examination, and certification of NDE personnel.			√		
Records of personnel qualification shall be prepared and maintained by the employer.					
2.4.2.3 Inspection Requirements					
A. Inspection Planning					
Inspection planning shall be performed and documented and shall include the			√		
 Identification of work operations where inspections are necessary Identification of the characteristics to be inspected and the identification of when, during the work process, inspections are to be performed 					
 Identification of inspection or process monitoring methods to be employed Identification of acceptance criteria Identification of sampling requirements Methods to record inspection results Selection and identification of the measuring and test equipment (M&TE) to be used to perform the inspection 					
8. Process used to ensure that the equipment being utilized for inspection or testing is calibrated and is of the proper type, range, accuracy, and tolerance to accomplish the intended function					
When statistical sampling is to be used to verify the acceptability of a group of items, the statistical sampling method shall be based on recognized standard practices.			√		
B. Inspection Hold Points					
Hold points are used to control work that is not to proceed without the specific consent of the organization placing the hold point. The specific hold points shall be indicated in implementing procedures. Only the organization responsible for the hold point may waive the hold point. Approval to waive specified hold points shall be documented before continuing work beyond the designated hold point.			√		

	QAPD (REV 3) REQUIREMENTS		PPLICA QUIREM DENTIFI	ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
C.	In-Process Inspections and Monitoring Items in process shall be inspected as necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be conducted when control is deemed inadequate using only one of these methods.			√		
	 When a combination of inspection and process monitoring methods is used, monitoring shall be performed systematically to ensure that the specified requirements for control of the process and the quality of the item are met throughout the duration of the process. Controls shall be established and documented for the coordination and sequencing of the work at established inspection points during successive stages of the process. 					
D.	Final Inspections					
	 Final inspections shall include a review of the results and the verification of the resolution of all nonconformances identified by earlier inspections. Finished items shall be inspected for completeness, markings, calibration, protection from damage, or other characteristics as required to verify the quality and conformance of the item to the applicable requirements. 			√		
	 Records review shall be performed to ensure adequacy and completeness. Item modifications, repairs, or replacements that are performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability. 					
E.	Inservice Inspections					
	 Required inservice inspection or surveillance of structures, systems, or components shall be planned and executed by or for the organization responsible for their operation. Inspection methods shall be established and executed to verify that the characteristics of an item continue to remain within specified limits. 			√		
	 Inspection methods shall include evaluations of performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate. 					

QAPD (REV 3) REQUIREMENTS	REC	PPLICA QUIREN DENTIF	IENTS	IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
F. Inspection Documentation Inspection documentation shall identify:			√		Items outside scope of SNL work.
 The item inspected and the date of the inspection The name or unique identifier of the inspector who documented, evaluated, and determined acceptability The method of inspection 			V		
 4. The inspection criteria, sampling plan, or reference documents (including revision designation) used to determine acceptance 5. The results 6. The M&TE used during the inspection, including the identification number and the calibration due date 7. Reference to any information on actions taken in connection with nonconformances, as applicable 					
2.4.2.4 Test Requirements					
Testing shall be used to determine the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions. Examples of such tests include prototype qualification tests, production tests, proof tests prior to installation, construction tests, and pre-operational tests.			√		
A. Test Planning					
Test planning shall include			√		
1. The identification of the implementing procedures to be developed to control and perform the test. In lieu of specially prepared written test procedures appropriate sections of related documents such as American Society for Testing and Materials (ASTM) methods may be used. If used, they shall incorporate the information directly into the approved test implementing procedure, or shall be incorporated by reference.			V		
 The identification of the item to be tested and the test requirements and acceptance limits, including the required levels of precision and accuracy 					
 The identification of the M&TE to be used to perform the test to ensure that the equipment being utilized is calibrated and is of the proper type, range, accuracy, and tolerance to accomplish the intended function 					
Any test prerequisites, including test equipment, instrumentation and software needs, personnel training and qualification, and suitably controlled environmental conditions					
5. Any mandatory hold points6. The methods that are to be used to record data					
and results 7. The provisions for ensuring that prerequisites for the given test have been met					

QAPD (REV 3) REQUIREMENTS	REQ	PLICAI UIREM ENTIFI	ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
B. Test Documentation					
Test documentation shall identify			√		
 The applicable test requirements, plans, and procedures, including revisions The item or work product tested The date of the test The name of the tester and data recorders 					
 5. The type of observation and method of testing 6. The identification of test criteria or reference documents used to determine acceptance 7. The results and acceptability of the test 8. The actions taken in connection with any noted nonconformances 9. The name of the person evaluating the test 					
results 10. The identification of the M&TE used during the test (including the identification number and calibration due date)					
C. Test Results					
Test results shall be documented and their conformance with acceptance criteria shall be evaluated by a qualified individual within the responsible organization to ensure that all test requirements have been satisfied.			√		
2.4.3 Monitoring, Measuring, Testing, and Data Collection Equipment				All of the procedure sections cited below for	
The following sections establish requirements to ensure that equipment used for inspection and testing is properly controlled, calibrated, and maintained. Equipment discussed in the following sections includes measuring and test equipment, measuring and data collection equipment,	√			compliance with QAPD section 2.4.3 are from NP 12-1, (except as noted for 2.4.3.1.C)	
equipment (either hand held or installed) used for data indication, and other equipment used for data indication, collection, or evaluation. These are termed M&TE.				The definition of M&TE is provided in the SNL NWMP Glossary.	
Calibration and control measures may not be required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy.	√			NP 12-1 Section 1.2	
2.4.3.1 Use and Control of M&TE					
Each organization using M&TE shall	√			NP 12-1 Sections 2.1 and 2.2 (for	
Establish and document a system to control the use and calibration of M&TE				use) and 2.3 (for calibration)	
B. Have a program to recall for calibration, or remove from service, M&TE that has exceeded its calibration interval; has broken calibration seals; has been modified, repaired, or has had components replaced; or is suspected to be malfunctioning because of mishandling, misuse, or unusual results				Section 2.4.2	

	QAPD (REV 3) REQUIREMENTS	REC	PPLICA QUIREM DENTIF	ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
C.	Establish and maintain documented procedures to evaluate the adequacy of the calibration system and to ensure compliance with the requirements of this QAPD, including the acquisition of calibration services from laboratories meeting the requirements of ANSI/NCSL Z540-1, Calibration Laboratories and Measuring and Testing Equipment – General Requirements	√			NP 18-1	The required evaluations are performed via audits or surveillances, governed by NP 18-1.
D.	Maintain records documenting that established M&TE schedules and procedures have been followed. These records shall include an individual record of calibration, or other means of control, providing: 1. A description or identification of the item 2. Calibration interval 3. Date calibrated 4. Identification of the calibration source 5. Calibration results (data and status) 6. Calibration action taken (adjusted, repaired, new value assigned, derated, etc.) 7. Evaluation and corrective action taken in response to out-of-calibration conditions	√			D.16. Sections 2.3.4, 9 th bullet D.7. Section 2.4.1 Calibration Records are prescribed in NP 12-1 Section 3.0	
E.	Label all M&TE to indicate the calibration status, the date calibrated, the calibration due date or usage equivalent, and the identification of any limitations. (When it is impractical to apply a label directly to an item, the label may be affixed to the instrument container or some other suitable means may be used to reflect calibration status.)	√			Section 2.3.2, 4 th para.	
F.	Evaluate the validity of previous inspection and test results and the acceptability of related items, data collected, and processes monitored, when M&TE is found to be out-of-calibration	√			Section 2.4.1, 3 rd para., 2 nd bullet	
G.	Handle, store, and transport M&TE in a manner that does not adversely affect the calibration or condition of the equipment	√			Section 2.2.2	
H.	Give due consideration to temperature, humidity, lighting, vibration, dust control, cleanliness, electromagnetic interference, and any other factors affecting the results of measurements. Where pertinent, these factors shall be monitored and recorded and, when appropriate, correcting compensations shall be applied to measurement results.	√			Section 2.2.1	
2.4	3.2 Calibration					
A.	M&TE requiring calibration shall be calibrated at periodic intervals established and maintained to ensure acceptable reliability, where reliability is described as the probability that M&TE will remain intolerance throughout the interval.	√			Section 2.3.1 (for obtaining cal. of M&TE) and 2.3.4, 3 rd bullet (for establishment of intervals)	
B.	Intervals shall be established for all M&TE requiring calibration unless the equipment is regularly monitored through the use of check standards in a documented measurement assurance process. Check standards must closely represent the item parameters normally tested in the process, and the check standard must be verified periodically.	√			Section 2.3.4, 3 rd bullet (for intervals) and section 2.1.1, note (for exception not requiring interval)	

	QAPD (REV 3) REQUIREMENTS	APPLICABL REQUIREMEN IDENTIFIED		ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
C.	Where intervals are used to ensure reliability, the interval setting system must be systematically applied and shall have stated reliability goals and a method of verifying that the goals are being attained.	√			Section 2.3.4, 3 rd bullet	
D.	Intervals may be based on usage or time since last calibration.	√			Section 2.3.4, 3 rd bullet	SNL does not utilize "usage" intervals.
E.	All exemptions from periodic calibration shall be approved and documented.	√			Section 2.1.1 note, and section 2.2.4	
F.	The recall system may provide for the temporary extension of the calibration due date for limited periods of time under specified conditions that do not unreasonably impair the satisfaction of task objectives.	√			Section 2.2.5	
G.	Calibration services shall conform to the requirements of ANSI/NCSL Z540-1, Calibration Laboratories and Measuring and Testing Equipment – General Requirements.	√			Section 2.3.4, 1 st bullet	
H.	If any M&TE is found to be significantly out-of- tolerance during the calibration process, the cognizant organization shall provide for the notification, to the user and cognizant QA management, of the out-of- tolerance condition with the associated measurement data so that appropriate action can be taken.	√			Section 2.3.4, 9 th bullet (notification to user and data) and section 2.4.1 (notification to cognizant QA management)	

Section 3 Assessment Requirements

Sandia National Laboratories ORGANIZATION

	QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
3.1	MANAGEMENT ASSESSMENT				NP 1-1	
per effe org exp hur	nagers at every level shall periodically assess the formance of their organization to determine the ectiveness of QA program provisions that enable the anization to meet customer requirements and ectations. This assessment shall emphasize the use of man and material resources to achieve organizational als and objectives.	√			Section 2.2.3	
A.	The management assessment should include an introspective evaluation to determine if the entire integrated management system effectively focuses on meeting strategic goals.	√			Sections 2.2.3.1 and 2.2.3.2	
В.	Managers shall retain overall responsibility for management assessments. Direct participation by senior management is essential to the success of the process because management is in the position to view the organization as a total system.					
C.	Management assessments should focus on the identification and resolution of both systemic and management issues and problems. Strengths and weaknesses affecting the achievement of organizational objectives should be identified so that meaningful action can be taken to improve quality.					
D.	Processes being assessed should also include strategic planning, organizational interfaces, cost control, use of performance indicators, staff training and qualifications, and supervisory oversight and support. Effective management assessments should evaluate such conditions as the state of employee knowledge, motivation, and morale; the amount of mutual trust and communication among workers and organizations; the existence of an atmosphere of creativity and improvement; and the adequacy of human and material resources.					
E.	Management assessments of the QA program shall be conducted regularly and reported at least annually to an identified senior management level with sufficient authority to effect corrective measures, as necessary.					
F.	Management assessment results should be used as input to the organizational continuous improvement process.					

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
3.2 INDEPENDENT ASSESSMENT 3.2.1 General Requirements Planned and periodic independent assessments shall be conducted to measure item and service quality, process effectiveness, and promote improvement. The organization performing assessments shall have sufficient authority and freedom from the activities being assessed to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable of the items and activities being assessed. The types and frequencies of independent assessments shall be based upon the relevant control levels assigned to the items and activities under the cognizance of the	√			All references identified in Section 3.2 are found in NP 18-1, except where otherwise noted NP 18-1 Section 2.1.2	
organization. 3.2.2 Additional Requirements The CAO and participant organizations responsible for the performance of activities important to compliance application, nuclear safety, waste characterization, or the isolation of waste within the disposal system shall implement a program of surveillance and audits. The program shall be planned and documented and shall include both routine surveillance of those activities and audits to verify compliance with all aspects of the quality assurance program and to determine its adequacy and effectiveness. The surveillance and audit program shall be implemented in accordance with the requirements of sections 3.2.3 and 3.2.4, respectively, in addition to the general requirements above.	√			Section 2.2.1	Audit and Surveillance schedules are maintained on the NWMP on-line documents Web site.
Surveillances A. A program of surveillance of the above referenced activities shall be planned, performed, documented, and reported to appropriate management personnel. The surveillance process consists of monitoring or observing to verify whether an item, activity, system, or process conforms to specified requirements.	√			Section 2.2	
 B. Surveillances shall accomplish the following: Monitor work in progress Document compliance or noncompliance with established requirements and procedures Identify actual and potential conditions adverse to quality Obtain timely corrective action commitment from cognizant managers for identified conditions adverse to quality Provide notification to responsible managers of the status and performance of work under surveillance Verify timely implementation of corrective action 	√			Section 2.2	

	QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
subj orga requ	its or other independent assessments of the ject activities, conducted by the responsible anization, may be counted as satisfying the uirement to do surveillances of related activities in corresponding surveillance schedule period.			√		SNL QA Program is more rigorous in this area and does not permit this activity to take place.
3.2.4	Audits				See Below	
The follo	owing describes the audit process requirements.	√				
A. Audi of a inter	Scheduling Audits lits shall be scheduled to begin as early in the life project or activity as practicable and continue at rvals consistent with the schedule for omplishing the work and commensurate with the igned control level.	√			NP 18-1 Section 2.2.1	Audit and Surveillance schedules are maintained on the NWMP on-line documents Web site.
supp surv base	odically scheduled QA program audits shall be plemented by, or integrated with, either audits or reillances of a technical nature (e.g., performance-ed audits) which assess the quality of selected k products and work processes.					
3.2.4.2	Planning and Preparation for Audits				Section 2.2.2	
	anization performing the audit shall develop and nt a plan for each audit.	√				
purp orga	plan shall include the scope, requirements, bose, audit personnel, activities to be audited, anizations to be notified, applicable documents, edule, and written procedures or checklists to be d.					
asse prob prob corre dete	it planning shall include a review of past essment results to determine the nature of plems that have occurred. When recurring plems are found, the audit team shall review ective actions that have been taken and attempt to ermine whether the corrective actions were ctive in preventing recurrence.					
back docu	it preparation shall include review of pertinent kground information, procedures, and technical uments so that audit team members are familiar the work being audited.					
appl	its shall include technical evaluations of the licable procedures, instructions, activities, and is, as appropriate.					
	scope shall include related corrective actions en since the previous assessment.					

QAPD (REV 3) REQUIREMENTS	REQ	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	Y N N/A			
3.2.4.3 Audit Team Selection				Section 2.2.2	
Audit team members shall be identified prior to the start of the audit activity. The team members shall be selected on the basis of technical qualifications and knowledge of the item or process being audited and shall be independent from the items or processes being audited. Audit team members shall have sufficient authority and organizational freedom to carry out their assigned responsibilities. In the case of internal audits, personnel having direct responsibility for performing the activities being audited shall not be involved in the selection of the audit team.	√				
A. An audit team leader shall be appointed to provide indoctrination and supervision of the team, organize and direct the audit, and coordinate the preparation and issuance of the audit report.					
B. Before starting the audit, the audit team leader shall ensure that the assigned personnel collectively have experience and training commensurate with the scope, complexity, or special nature of the work to be audited.					
C. Technical specialists, with appropriate technical expertise or experience in the work being audited, shall be used when auditing the adequacy of technical processes.					
3.2.4.4 Auditor Qualification				Section 2.1.3	
Auditors shall be technically qualified in their assigned roles. In addition, they shall have appropriate training or orientation to develop their competence for performing audits. Competence of personnel performing various audit functions shall be developed by the following methods:	√				
Orientation to provide a working knowledge and understanding of the program QA requirements and implementing procedures used to perform audits and report audit results.					
B. Training that provides fundamentals, objectives, and techniques of performing audits. Training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of evaluating the effectiveness of corrective actions for conditions adverse to quality.			1		
C. On-the-job training, guidance, and counseling under the direct supervision of a lead auditor may be substituted for the training above. Such training shall include planning, performing, reporting, and follow-up actions.					
3.2.4.5 Technical Specialist Qualification				Section 2.1.3.2	
Technical specialists selected for audit assignments shall receive indoctrination commensurate with the scope, complexity, or special nature of the work being audited. In addition, they shall be trained to the requirements of the audit process associated with their duties.	√				

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
3.2.4.6 Lead Auditor Qualification				Section 2.1.3.3	
A lead auditor shall be capable of organizing and directing audits, reporting audit results, and evaluating planned and implemented corrective action. A lead auditor also shall be certified as meeting the requirements provided in this section for education and experience, communication skills, training, audit participation, and the successful completion of a lead auditor examination.	√				
A. Lead Auditor Education and Experience				Section 2.1.3.3	
The prospective lead auditor shall have verifiable evidence that a minimum of 10 credits have been accumulated under the following scoring system:	√				
Education (four credits maximum)				NP 18-1	
 a. An associate's degree from an accredited institution scores one credit. If the degree is in engineering, physical sciences, mathematics, or QA, it scores two credits. 	√			Appendix B	
 b. A bachelor's degree from an accredited institution scores two credits. If the degree is in engineering, physical sciences, mathematics, or QA, it scores three credits. In addition, score one more credit for a master's degree (or higher) in engineering, physical sciences, business management, or QA from an accredited institution. 					
Experience (nine credits maximum)				Appendix B	
The prospective lead auditor shall have participated in a minimum of five QA audits or equivalent verifications (such as management assessments, pre-award surveys, or comprehensive surveillance, as long as the parameters of the audit process are met) within three years prior to the certification, one of which shall be a nuclear QA audit within the year prior to qualification. In addition, for technical experience in such areas as scientific investigation, site characterization, nuclear waste management, production, transportation, engineering, manufacturing, construction, operation, or maintenance, or experience applicable to the auditing organization's area of responsibility, score one credit for each full year, with a maximum of five credits for this aspect of experience.	√				
a. If two years of this experience have been in a nuclear field, score one additional credit.					
 b. If two years of this experience have been in QA, score two additional credits. 					
 c. If two years of this experience have been in auditing or assessment, score three additional credits. 					
d. If two years of this experience have been in nuclear-related QA, score three additional credits.					

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
e. If two years of this experience have been in nuclear-related QA auditing or assessment, score four additional credits.	V			Appendix B	
Professional Competence (two credits maximum)				Appendix B	
For certification of competency in engineering, science, or QA specialties, issued and approved by a state agency or national professional or technical society, score two credits.	√				
4. Rights of Management (two credits maximum)				Appendix B	
When determined appropriate, the organization performing the qualification may grant up to two credits for other performance factors applicable to auditing that are not explicitly called out in this section (such as leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and completed QA training courses).	√				
B. Lead Auditor Communication Skills				Appendix B	
The prospective lead auditor shall have the capability to communicate effectively, both in writing and orally. These skills shall be attested to in writing by the candidate's supervisor.	√				
C. Lead Auditor Training				NP 18-1	
Prospective lead auditors shall be trained to the extent necessary to ensure their competence in skills as established by the organization responsible for performing audits. Training in the following areas shall be accomplished and its completion verified based upon a management evaluation of the particular needs of each prospective lead auditor:	√			Section 2.1.3.3	
Knowledge and understanding of the participant organization's QA program and other program-related procedures, codes, standards, regulations, DOE orders, and regulatory guides					
General structure of QA plans and implementation procedures, as a whole					
Auditing techniques of examining, questioning, evaluating, reporting, and methods of identifying, following up, and closing corrective action items					
4. Audit planning in functional areas of nuclear QA					
D. Lead Auditor Examination				Section 2.1.3.3	
The prospective lead auditor shall pass an examination that evaluates his or her comprehension of and ability to apply the audit knowledge described in this section. The test shall be oral, written, practical, or any combination of these methods.	√				

		QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
			Υ	N	N/A]	
		The development and administration of the examination for a lead auditor is the responsibility of the organization responsible for the auditing program. This organization shall:	√			Section 2.1.3.3	
		Maintain the integrity of the examination through confidentiality of files and, where applicable, proctor examinations					
		 Develop and maintain objective evidence regarding the type and content of the examination 					
E.	Lea	nd Auditor Certification				Section 2.1.3.4	
resp	onsi	ditors shall be certified by the organization ble for the auditing program as being qualified to its. This certification will document the	√			Appendix B	
	1.	Name of the organization performing the certification					
	2.	Name of the lead auditor					
	3.	Date of certification or recertification					
		Basis of certification (such as education, experience, communication skills, and training)					
		Signature of the designated representative of the organization responsible for the certification					
F.	Lea	nd Auditor Proficiency Maintenance				Section 2.1.3.5	
		Lead auditors shall maintain their proficiency through one or a combination of the following:	√			Appendix C	
		Regular and active participation in the audit process					
		 Review and study of codes, standards, QA implementation procedures, instructions, and other documents related to QA program auditing 					
	2.	c. Participation in training programs Management of the auditing organization shall evaluate the proficiency of lead auditors annually. Based on the evaluation, management shall choose to extend the qualification, require retraining, or require requalification. Management evaluations shall be documented.					
		Lead auditors who fail to maintain their proficiency for a two-year period shall require requalification to the requirements of this section of the QAPD. However, participation in only one nuclear audit is required.					
		Performing Audits its shall be performed using the written procedures	,			NP 18-1 Section 2.2.2	QAPD Section 3.2.4.7, see NP 18-1 Section 2.2.2
		ted to the activity being audited or checklists.	√				

	QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
E	Elements that have been selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if those elements are being implemented effectively.					
	c. Audit results shall be documented by audit personnel and reported to and reviewed by management having responsibility for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.					
	 Conditions adverse to quality shall be documented and corrected according to the requirements of section 1.3.2. 					
3	.2.4.8 Reporting Audit Results				NP 18-1	
T te	the audit report shall be prepared and signed by the audit earn leader and issued to the management of the audited rganization and any affected organizations. The audit eport shall include the following, as appropriate: A description of the audit scope	√			Section 2.2.2	
Е	. The identification of the auditors					
C	 The identification of persons contacted during the audit 					
С	A summary of the documents reviewed, persons interviewed, and the specific results of the reviews and interviews (i.e., a summary of the checklist contents)					
E	A summary of audit results, including a statement of the QA program adequacy, implementation, and effectiveness as appropriate to the scope					
F	A description of each reported condition adverse to quality in sufficient detail to enable corrective action to be taken by the audited organization					
C	A description of commendable quality practices					
d d ir c	additionally, common audit findings shall be grouped in the eport whenever possible so that related or systematic reakdowns in the QA program are identified. Findings or eficiencies shall be categorized based on their relative inportance to indicate their degree of impact on compliance assessment, nuclear safety, waste haracterization, waste isolation, environmental protection, in the QA program.	√			Section 2.2.2	
3	.2.4.9 Audit Response and Follow Up				NP 18-1	
c re th re	Management of the audited organization will investigate onditions adverse to quality; determine and schedule orrective action, including measures to preclude ecurrence; and notify the auditing organization in writing of the actions planned or taken. The adequacy of audit esponses shall be evaluated by or for the auditing rganization. Follow-up action shall be taken to verify that orrective action is accomplished as scheduled.	√			Section 2.2.2	

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
3.2.4.10 Audit Records The following documents, when developed in fulfillment of the audit requirements of this QAPD, shall be controlled as QA records in accordance with section 1.5 of this QAPD: audit plans, audit reports, audit checklists, audit responses, and documentation of corrective action completion and follow-up.	√			Section 3.0	

Section 4 Sample Control Requirements

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	QAPD (REV 3) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED		IENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
4.1	GENERAL				See Below	
	e following general requirements apply to sample trol:	√				
A.	Samples shall be controlled and identified in a manner consistent with their intended use.	1			NP 13-1 Section 1.0	
B.	Implementing procedures shall define responsibilities, including organizational interfaces, related to documenting and tracking sample possession from sample collection and identification through handling, preservation, shipment, transfer, analysis, storage, and final disposition.					
C.	Sample control measures shall include provisions for the identification of the in situ orientation of samples, where appropriate.					
D.	A chain of custody record form shall be maintained. The chain of custody record shall provide a document trail of all persons who have custody of a given sample, including the date and time of its transfer.	1			SP 13-1	
E.	Sample control measures, including identification and documentation, shall ensure that samples can be traced at all times, from collection through final disposition.	√			NP 13-1 Section 2.2	
F.	Where samples have a maximum life expectancy or expiration date, methods shall be employed that preclude the use of the sample beyond its specified life.	√			Section 2.5	
G.	Representative archival samples from difficult-to- repeat sample collection activities, such as principal bore holes, shall be maintained.	√			Section 2.2 (Note)	
H.	Implementing procedures shall specify the representative samples to be archived if the need to archive samples is identified.					
4.2	SAMPLE IDENTIFICATION	√			NP 13-1	
A.	Each sample shall be uniquely identified from its initial collection through the final disposition of the sample.				Section 2.2	
B.	Sample identification shall be verified and documented before each transfer or release for testing, analysis, or disposition.	1			Section 2.2	

QAPD (REV 3) REQUIREMENTS	REC	PPLICA QUIREM DENTIFI	ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
C. Identification shall be maintained by placing the identification directly on the samples wherever possible or in a manner that ensures that identification is maintained. If direct physical markings are either impractical or insufficient, other appropriate means shall be employed (e.g., physical separation, labels or tags attached to containers, or procedural control). When used, physical markings shall	√			Section 2.2	
Be applied using materials and methods that provide a clear and legible identification					
Not affect the sample content or form					
Be transferrable to each identified sample part when the sample is subdivided					
Not be obliterated or hidden by surface treatments or sample preparation unless other means of identification are substituted					
D. If sample storage is required, then methods shall be established for the control of sample identification that are commensurate with the planned duration and storage conditions. These methods shall provide for, as applicable	√			Section 2.4	
The maintenance or replacement of markings and identification tags that have been damaged during handling or aging					
The protection of identification markings from excessive deterioration due to environmental exposure					
4.3 HANDLING, STORING, AND SHIPPING SAMPLES					
Handling, storing, cleaning, packaging, shipping, and preserving samples shall be conducted in accordance with established work and inspection implementing procedures. Controls shall provide for the maintenance of sample characteristics, sample integrity, and sample identification during storage.	√			NP 13-1 Section 2.4	
A. The controls shall be consistent with the planned duration and storage conditions and shall describe actions to be taken where maximum sample life expectancy limits are identified.	√			Section 2.5	
Storage methodology shall be developed and implemented to ensure that samples are maintained in predetermined environmental conditions commensurate with their intended use and purpose.	√			Section 2.4	
Samples shall be controlled to preclude the mixing of like samples.	√			Section 2.5	
Samples on which analysis or tests have been performed shall be identified and maintained in a separate part of the storage area.	√			Section 2.5	
E. If required for critical, sensitive, perishable, or high-value samples, specific measures for the handling, storage, cleaning, packaging, shipping, and sample preservation shall be identified and used.	√			Section 2.4	

	QAPD (REV 3) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED		ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
F.	Measures shall be established for sample marking and labeling for packaging, shipping, handling, and storage as necessary to adequately identify, maintain, and preserve the sample. Markings and labels shall indicate the need for and the presence of special environments or the need for other special controls, if necessary.	√			Section 2.2	
G.	Samples requiring special protective equipment (such as containers) and special protective environments (such as inert gas or limits on moisture and temperature) shall be specified, employed, verified, and documented.	√			Section 2.4	
4.4	DISPOSITION OF NONCONFORMING SAMPLES				NP 13-1	
Α.	Samples that do not conform to requirements specified in work controlling documents (such as job packages, travelers, or work requests) shall be identified, documented, evaluated, and segregated in accordance with section 1.3.				Section 2.3	
B.	The disposition for nonconforming samples shall be identified and documented and shall be limited to "use-as-is," "limited use," or "discard."					
C.	Samples that have lost their identity shall be documented as nonconforming and shall not be used.					

Section <u>5 Scientific Investigation Requirements</u>

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			PPLICA QUIREM DENTIF	IENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
ver scie Tes sha sec Rec and sup	entific investigations shall be defined, controlled, ified, and documented. Process variables affecting entific investigations shall be measured and controlled. It processes conducted in support of such investigations and be controlled in accordance with the requirements of the controlled in accordance with the requirements of this section.	√			NP 20-1 NP 20-2	
5.1 A.	PLANNING SCIENTIFIC INVESTIGATIONS Variables that affect interrelated scientific investigations shall be identified and controlled appropriately in each related investigation.	√			NP 20-1 Appendix A	
B.	The intended use of the data shall be documented before collection as part of the planning for data processing. Any alternate use of the data shall be evaluated for appropriateness and the justification for use shall be documented.	√			NP 20-1 Appendix A	
C.	Planning shall consider the compatibility of data processing with any conceptual or mathematical models used at each applicable stage.	√			NP 20-1 Appendix A	
D.	The technical adequacy of procedures for conducting scientific investigations and their implementation shall be reviewed and approved by qualified persons other than those who prepared the procedures. Changes to procedures for conducting scientific investigations shall be reviewed and approved in a manner commensurate with the original procedure.	√			NP 20-1 Sections 2.3 and 2.4 NP 6-1	
E.	Development activities used to establish new methods or procedures for conducting scientific investigations shall be documented. The results of developmental testing shall be reviewed for adequacy and approved by qualified persons prior to implementation of the procedures for data collection.	√			NP 20-1	"New methodologies conducted in laboratory or field activities" is the SNL terminology for developmental testing.
F.	Planning shall be coordinated with organizations providing input to or using the results of the investigation.	√			NP 20-1 Appendix A	
G.	Planning shall include the establishment of acceptance criteria for data quality evaluation to ensure that the data generated are valid and satisfy documented requirements for the following characteristics, as appropriate: data precision, data accuracy, data representativeness, data comparability, and data completeness.			√		Based on Section 5.3.21.1 of the CCA, these characteristics are not applicable.

	QAPD (REV 3) REQUIREMENTS		PPLICA QUIREM DENTIF	ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
H.	Planning shall include the identification of known sources of error and uncertainty as well as any input data that are suspect or whose quality is beyond the control of the performing organizations.	√			NP 20-1 Appendix A	
5.2	PERFORMING SCIENTIFIC INVESTIGATIONS				NP 20-1	
A.	Scientific investigations shall be performed in accordance with requirements documented in test plans, procedures, and scientific notebooks.	√			NP 20-2	
В.	If deviation from test standards or the establishment of specially prepared test procedures is deemed appropriate (e.g., no nationally recognized test standards exist), the modified or new test procedures shall be documented in sufficient detail to be repeatable and shall be justified, evaluated, and approved by the cognizant technical organization.	√			NP 20-1 Appendix A	
C.	Scientific notebooks shall contain, at a minimum: 1. A statement of the objective and description of work to be performed or reference to an approved plan that describes the work	√			NP 20-2 Section 2.2	
	2. The method(s) used					
	3. Identification of the samples					
	4. The M&TE used					
	 A description of the work performed and the results obtained, the names of individuals performing the work, and dated initials or signature, as appropriate, of individuals making the entries 					
	A description of changes made to methods used, as appropriate					
	 The potential sources of uncertainty and error in test plans, procedures, and parameters that must be controlled and measured to ensure that tests are valid 					
D.	Scientific results shall be periodically reviewed by an independent qualified individual to verify that there is sufficient detail to retrace the investigation and confirm the results, if feasible, or repeat the investigation and achieve comparable results without recourse to the original investigator.	√			NP 20-2 Section 2.3	
E.	Practices, techniques, equipment, and manual or computerized methods used to obtain and analyze data shall be verified to ensure that they are technically sound and have been properly selected. Controls shall be established for these processes to ensure that they are properly implemented, including controls to prevent tampering.	√			NP 20-1 Appendix A	"practices"=primary tasks & conduct. "techniques"=sample/ data quality control "equipment"=M&TE "obtain & analyze data"=DAS, data identification and use.

	QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
F.	Data collection and analysis shall be controlled by procedures of sufficient detail to allow the processes to be repeated. Where appropriate, quality control checks shall be performed using recognized methods such as replicate, spike, and split samples; control charts; blanks; reagent checks; replication of the methods used to obtain the results; or alternate analysis methods.	√			Appendix A	
G.	Test media (e.g., fluids), when used, shall be characterized and controlled in accordance with test procedures.	√			Appendix A	
H.	Scientific notebooks and technical implementation documents shall be maintained as QA records.	√			NP 20-2 Section 3	
5.3 . A.	All data shall be recorded so that they are clearly identifiable and traceable to the test, experiment, study, or other source from which they were generated. Identification and traceability of the data shall be maintained for the lifetime of the WIPP.	√			NP 9-2 Appendix A for data entry NP 20-1 Appendix A and Section 2.6	
В.	The method of data recording (e.g., scientific notebooks, log books, data sheets, or computerized instrumentation systems) shall be controlled to avoid data loss and permit data retrievability. Controls shall be established to ensure that data integrity and security are maintained wherever data are stored. Controls shall prescribe how specific types of data will be stored with respect to media, conditions, location, retention time, security, and access. Data shall be suitably protected from damage and destruction during their prescribed lifetime and shall be readily retrievable.	√			NP 9-2 Appendix A for data entry NP 20-1 Appendix A NP 17-1 SP 17-1 SP 9-5 for data maintenance	
C.	Data transfer and reduction controls shall be established to ensure that data transfer is error free (or within a prescribed permissible error rate), that no information is lost in transfer, and that the input is completely recoverable. Data transfer and reduction will be controlled to permit independent reproducibility by another qualified individual. Examples of data transfer include copying raw data from a notebook into computerized data form or copying from computer tape to disk.	√			NP 9-2 Appendix A for data entry NP 20-1 Appendix A SP 9-5 for data maintenance	
D.	Data that are determined to be erroneous, rejected, superseded, or otherwise unsuited for their intended use shall be controlled to prevent their inadvertent use. Controls shall include the identification, segregation, and disposition of inadequate data. The basis for the disposition of erroneous data shall be justified and documented.	√			NP 9-2 Appendix B for parameter problem reports NP 20-1 Appendix A	
E.	All processes which change either the form of expression or quantity of data, values, or number of data items (data reduction) shall be controlled by prescribed methods that allow for the validation of the conversion process.	√			NP 20-1 Appendix A NP 9-1; Routine Calcs NP 9-2 Section 2.3 for changes Appendix A for data entry	

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
F. Data collection and analysis shall be critically reviewed and questions resolved before the results are either used or reported. Uncertainty limits shall be assigned to the data prior to their use.	√			NP 20-1 Section 2.6 NP 9-1 App A #1 for	
				uncertainty limits NP 9-2 Appendix A for data entry	
5.3.2 Data Validation Data validation is a systematic process used to review data to ensure that the required data quality characteristics have been obtained. Results of the review may require that qualifiers be placed on the use of the data.	√			The entire QA program contributes to data validation for Section 5.3.2 by way of technical reviews, NP 6-1, in both planning (NP 20-1 Test Plans, NP 9-1 Analysis Plans), implementation [NP 20-2 Scientific Notebooks, Activity/Project Specific Procedures (SPs)] and NP 9-2 Appendix A for data entry.	
A. Validation methods shall be planned and documented. The documentation shall include the acceptance criteria used to determine if the data are valid.	V			The entire QA program contributes to data validation for Section 5.3.2 by way of technical reviews, NP 6-1, in both planning (NP 20-1 Test Plans, NP 9-1 Analysis Plans), implementation [NP 20-2 Scientific Notebooks, Activity/Project Specific Procedures (SPs)] and NP 9-2 Appendix A for data entry.	
 B. All applicable data collected shall be validated. Validation shall include the following: 1. The relevant documentation is reviewed to evaluate the technical adequacy, the suitability for the intended use, and the adequacy of the QA record. 2. The results of the data review shall be documented. 3. The reviewer shall be independent of the collection activities. 	√			The entire QA program contributes to data validation for Section 5.3.2 by way of technical reviews, NP 6-1, in both planning (NP 20-1 Test Plans, NP 9-1 Analysis Plans), implementation [NP 20-2 Scientific Notebooks, Activity/Project Specific Procedures (SPs)] and NP 9-2 Appendix A for data entry.	

	QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
		Υ	N	N/A		
C. inde	Data validation shall be controlled to permit pendent reproducibility by another qualified individual.	√			The entire QA program contributes to data validation for Section 5.3.2 by way of technical reviews, NP 6-1, in both planning (NP 20-1 Test Plans, NP 9-1 Analysis Plans), implementation [NP 20-2 Scientific Notebooks, Activity/Project Specific Procedures (SPs)] and NP 9-2 Appendix A for data entry.	
han valid	Data considered as established fact by the scientific engineering community, such as engineering dbook data, critical tables, etc., do not require lation.	√			NP 9-2 Section 7.1.2 "Reference Parameters"	
This qual supple collection with not subject on provential conditions and the interior and	section contains requirements unique to the post ification of data and information that are relied upon to cort the WIPP compliance application and were exted prior to the implementation of this QAPD. While qualification process shall be conducted in accordance the program control requirements of this QAPD, it is intended that this QAPD identify the data that are extended to this process or the technical requirements of the ification process. The qualification process shall be ducted in accordance with approved procedures that ide for documentation of the decision process, the ors used in arriving at the choice of the qualification and, and the decision that the data are qualified for intended use.			√		This activity for Section 5.4 was completed when the CCA was submitted in 10/96.
	ting data shall be qualified using one or a combination e following methods: Determination that the data were collected under a QA program that is equivalent in effect to ASME NQA-1-1989 edition; ASME NQA-2a-1990 addenda, Part 2.7, to ASME NQA-2-1989 edition; and NQA-3-1989			~		
2.	The use of corroborating data, with the data relationships and inferences clearly identified and justified					
3.	Confirmatory testing that is performed and documented					
4.	Peer review conducted in a manner that is compatible with NUREG-1297, Peer Review for High-Level Nuclear Waste Repositories					

Section 6 Software Requirements

Sandia National Laboratories

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QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
6.1 GENERAL This section of the QAPD establishes software quality assurance (SQA) requirements for CAO participants who develop, procure, maintain, or use computer software that is important to compliance application and waste characterization.	√			NP 19-1	
A. The requirements in this section apply to computer software used in the manipulation or production of data that are, in turn, used in the processing, gathering, or generation of information whose output is relied upon to make design, analytical, operational, or compliance-related decisions with respect to the performance of the waste confinement, waste characterization, waste transportation, or waste acceptance processes. The application of these requirements shall be prescribed in written plan(s), policies, procedures, or instructions.	√			NP 19-1 Section 1.0	
B. The General Requirements defined in this section apply to those activities involved in the processing, control, or measurement of the hazardous, radioactive, and waste matrix materials of the TRU or mixed TRU waste. Waste matrix materials include but are not limited to metals, cellulosics, chelating agents, water, and other liquids, plastics, and rubber.			√		Not applicable to SNL scope of work.
C. The Additional Requirements defined in this section apply only to software used in the processing, control, or measurement of the radioactive and waste matrix materials of the TRU waste.			√		Not applicable to SNL scope of work.
D. Exempt from the requirements of this section of the QAPD is software that is considered to be "systems software," (e.g., operating systems, administrative and management systems, system utilities, compilers, assemblers, translators, interpreters, query languages, word processing programs, spreadsheets, database managers, and graphing programs) or other software that does not generate data that are used in the formulation of conclusions. Software utilized in conjunction with the Supplemental Environmental Impact Statement is also excluded from the requirements of this section since it does not generate data used in the formulation of conclusions related to regulatory compliance. However, specific applications supporting section 6.2A., written for use within these types of software (e.g., detailed formulas or macros) that can be verified by hand calculations or other means shall meet the following requirements of this section:	√			NP 19-1 Section 1.0	

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
A listing of the version of the software used shall be developed and maintained.	√			NP 9-1 Appendix C, #6	These are identified as routine calculations
Documentation shall be prepared to indicate that the specific application provides the correct results for the specified range of input parameters.	√			NP 9-1 Appendix C, #6	under the NWMP QA program
 6.2.1 Inventory and Classification of Software 6.2.1.1 General Requirements A. An inventory of all applicable software shall be maintained that identifies the software name, version, classification, exemption status, operating environment, and the person and organization responsible for the software. B. Software governed by this section of the QAPD shall be categorized. The criteria for classification shall be documented in the inventory and shall address the purpose of the software relative to its use in engineering, scientific, testing, data collection, design, analysis, and operations activities, as well as its importance to safety or its significance in managing information or augmenting mission-essential decisions. 	√			NP 19-1 Sections 2.3.7.2, 2.3.7.4, and Appendix J	A. All "applicable software" is Compliance Decision (CD) software. B. Software (CD&PD) usage is classified per NP 9-1, Section 2.1.
6.2.2 Software Quality Assurance 6.2.2.1 General Requirements Controls governing applicable software development projects shall be identified in controlled and documented plans. The plans shall be formally reviewed and approved. Controls governing the configuration and use of the software shall be identified in plans or procedures appropriate to the organization(s) using the software. The following activities shall be addressed in plans or procedures: A. Software development B. Software verification and validation	√			NP 9-1 Appendix A,D NP 19-1 Section 2.1 Appendix B, C,D	
C. Software configuration control					
D. Software operation and maintenance					
Plans may be issued separately or as a single, composite plan, depending upon the nature and complexity of the project. The software control plans may be a section of the overall project plan, provided that each software item is addressed and the software control portion of the plan prescribes the documentation, reviews, and controls required by this section.	√			NP 19-1 Section 2.3.1	

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
6.2.2.2 Additional Requirements					
Plan(s) for ensuring software quality shall be prepared for each new software project at the start of the software life cycle. For procured software the software quality plan shall be prepared before the software enters the purchaser organization. Plan(s) may be prepared individually for each software project, may exist as a generic document to be applied to software prepared within or procured by an organization, or may be incorporated into the overall quality assurance program. The plan shall identify:	√			NP 19-1 Section 2.3.1	
A. The software products governed by the plan	√			NP 19-1 Section 2.2.1	
B. The types of documentation to be prepared, reviewed, and maintained during the software design, development, implementation, test, and use	√			NP 19-1 Section 2.2 and 2.3.1	
C. The organizations responsible for performing the work and achieving software quality and their tasks and responsibilities	√			NP 19-1 Section 2.3.1	
D. The process for reporting and documenting software discrepancies, evaluating the impact of discrepancies on previous calculations, and determining the appropriate corrective action(s)	√			NP 19-1 Section 2.3.7.3	
E. The standards, conventions, techniques, or methodologies that guide the software development, as well as the methods used to ensure implementation of requirements	√			NP 19-1 Section 2.3.1	
F. The procedure(s) used for establishing and maintaining the integrity of data, embodied mathematical models, and output files	√			NP 19-1 Table 1 and Section 2.3.1	F. Integrity of data is governed by NP 9-1, Appendix B.
6.3 SOFTWARE PROCUREMENT					
6.3.1 General Requirements					
This section of the QAPD identifies responsibilities of the sponsoring organization for procured software upon receipt of the software.	√			NP 19-1 Section 2.2.1	
All procured software governed by this section shall be tested in accordance with documented and approved test procedures using approved test-case specifications to ensure that the procured software will perform satisfactorily in its operating environment. The installation tests (including the test procedures), the test case specifications, and the results of the installation tests shall be identified, documented, and maintained as records according to established procedures.	√			NP 19-1 Section 2.2.1	'Procured' software falls under the category of Acquired software. Requirements for acquired software, including test case specifications, documentation, etc., are identified in Table 1 Life Cycle Software Requirements and Section 2.2.1.
 A. The procurement of software and related services shall be performed in accordance with section 2.3 of this QAPD. 	√			NP 4-1	

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
B. Once the software has been installed, but before its use, the sponsoring organization shall perform user acceptance to verify the functional capability of the software and the acceptability of the supplier supporting documentation (e.g., the user manual, technical specification, and the results of supplier testing).	√			NP 19-1 Section 2.2.1	B. All CD software used on WIPP program falls under NP 19-1, Section 2.2 for both procured and software developed in-house. Requirements in Section 2.2 for CD software include testing to verify functional capability and evaluation of supporting documentation.
C. For procured software, the supplier shall report software errors and failures to the sponsoring organization. The sponsoring organization shall also report software errors to the supplier.	√			NP 4-1 NP 19-1	Contracts for procured software must comply with all QAPD requirements (as defined by their own program) and is required by NP 4-1, section 2.1.3. Software under the SNL QA program is addressed in NP 19-1, section 2.3.7.3.
6.4 SOFTWARE DEVELOPED UNDER OTHER QA					
PROGRAMS					
6.4.1 General Requirements					
Software that has not been developed or approved in accordance with this QAPD shall be evaluated to determine adequacy to perform its intended functions. The evaluation shall be documented. The software shall be uniquely identified and controlled prior to the evaluation, clearly traceable to the software requirements, accepted by the sponsoring organization, and placed under configuration control prior to use.	√			NP 19-1 Section 2.2.1 Appendix B	
6.4.2 Additional Requirements				NP 19-1 page 8 Table	
The evaluation of existing software developed in accordance with other QA programs shall serve as the basis to A. Determine the adequacy of existing verification and	√			Notes #4 Section 2.2.1 item A	As software is modified, it is required that all baseline components be evaluated for impact, including the Design
A. Determine the adequacy of existing verification and validation activities and software documentation to support operation and maintenance					Document.
B. Identify the activities to be performed and the documentation necessary to accept the software for its intended use and place it under configuration control. The evaluation shall be documented and contain at a minimum:	√			NP 19-1 Section 2.2.1	
User application requirements					
Test plans and test cases required to validate the software acceptability					
User documentation as described in section 6.8.2.6					

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		UIREMENTS		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A				
6.5 SOFTWARE DEVELOPMENT AND LIFE CYCLE							
6.5.1 General Requirements The developmental activities of software projects subject to this QAPD shall be identified in documented and approved plans to ensure that the project proceeds in an orderly and traceable manner. Sufficient information shall be provided to clearly indicate the necessary tasks, the deliverables and the baselines for each phase, the required reviews, appropriate milestones, and the responsibilities associated with each task.	√			NP 19-1, Section 2.3.1, Appendix B			
Software project development plans shall identify the items that need to be baselined and the methods to be used for controlling the configuration of those baselines throughout the development process. Configuration control planning for software is addressed in section 6.7 of this QAPD.							
 A. The activities associated with the evolution of the software shall be accomplished using an iterative or sequential approach. The approach shall include the analysis of the problem under study, the transformation of the analysis into the design, the implementation of the design into validated computer software, and the development of sufficient documentation to demonstrate that the specified requirements have been successfully included in the computer software. 	√			NP 19-1 Section 2.3 Table 1			
 B. The iterative or sequential approach to software development consists of phases, with each phase leading to the development of a specific work product representing components of the software baseline. The software phases are: Definition of requirements Design Implementation Testing Installation and checkout Operations and maintenance Retirement C. Following the development of the software quality plan, 	√			NP 19-1 Section 2.3 Table 1			
no strict sequence of performing activities is required (i.e., activities may be performed serially or recursively) provided that all the specified requirements for each software development phase have been met and the intent of the requirements has not been subverted.	√			NP 19-1 Section 2.3			

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		REQUIREMENTS		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A				
6.5.2.1 Requirements Phase Software requirements shall be specified, documented, and reviewed. These requirements shall pertain to functionality, performance, design constraints, data attributes, and external interfaces (e.g., hardware limitations) as outlined in section 6.8.2.2. Each requirement shall be specified in sufficient detail to permit the accomplishment of design and validation activities. Software requirements shall be traceable throughout the software development cycle, and a verification and validation plan shall be prepared after the software requirements have been documented and approved.	√			NP 19-1 Section 2.3.2 Appendices C and D			
6.5.2.2 Design Phase The software design shall be based on the software requirements and shall be documented and reviewed. The design shall specify the overall structure (control and data flow) and the reduction of the overall structure into physical solutions (algorithms, equations, control logic, and data structures). The design may necessitate the modification of the requirements documentation and the verification and validation plans.	V			NP 19-1 Section 2.3.3 Appendix E			
6.5.2.3 Implementation Phase The software design shall be translated into a form (programming language) suitable for processing by a computer.	√			NP 19-1 Section 2.3.4 Appendix F			
The executable software shall be analyzed to identify and correct errors.	√			NP 19-1 Appendix H, Appendix I			
Test requirements and acceptance criteria shall be specified, documented, and reviewed and shall be based upon applicable design or other pertinent technical bases. Appropriate tests, such as design-driven tests, requirements-driven tests, hardware integration tests, and in-use tests, shall be controlled. Software testing, using documented test plans, test cases, and test results are the primary methods of software validation.	√			NP 19-1 Section 2.3.2 and 2.3.5 Appendix D, H			
Testing of software shall be performed to the extent that unintended functions are identified and reviewed and their impact determined and corrected. If appropriate, determine if modifications of the requirements, the design, the implementation, or the test plans and test cases are required.	√			NP 19-1 Appendix D #7			
Design-driven tests shall be used to demonstrate the capability of the software to produce valid results for test problems encompassing the range of intended use as defined by the software documentation. Testing of software used for operational control shall demonstrate the required performance over the entire range of the controlled function or process. Acceptable test methods consist of:	√			NP 19-1 Appendix D, H			

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Y	N	N/A		
A. Hand calculations	√			NP 19-1 Appendix D, H	
B. Calculations using comparable proven problems					
C. Empirical data and information from confirmed published data and correlations or technical literature					
Comparison with other validated software of similar purpose					
E. Manual inspections or qualitative checks not involving numerical manipulation (examples include visual inspection of database reformatting or data plotting).					
Requirements driven tests shall be used to validate software by comparing test results of software execution with objective evidence obtained by the above methods. The results of this evaluation shall be of sufficient scope and depth to prove the capabilities and limitations delineated in the software documentation.	√			NP 19-1 Appendix H	
6.5.2.5 Installation and Checkout Phase					
 A. During installation and checkout, the software becomes part of a system consisting of applicable software components, hardware, and data. The process of integrating the software with other applicable components may consist of installing both the hardware and software, initializing or creating databases, and verifying that all components of the system have been included in the installation. Test problems shall be developed and documented to permit confirmation of the acceptable performance of the software in its operating environment. Installation and checkout of software shall consist of the 1. Execution of tests for installation and integration 2. Documented acceptance of the software for operational use 3. The placement of the software under 	√			NP 19-1 Section 2.3.6	
configuration control prior to use B. Completion of the installation and checkout activities	1			NP 19-1	
establishes the software baseline.				Section 2.3.7.4	
6.5.2.6 Operations and Maintenance Phase Operation of the software is conducted by the user in accordance with the operation and usage instructions described in the software user documentation. Once the software has been made available for use, the software requirements and the design integrity shall be maintained. Maintenance activities shall be performed in a traceable, planned, and orderly manner.	V			NP 19-1 Sections 2.3.4 and 2.3.7 Appendices F, G, and J	
In all cases, verification and validation of software shall be completed and approved and corrective actions performed, as necessary, prior to relying upon the software to perform its intended function.					

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
A. Post Installation Maintenance Software shall be maintained to remove latent errors (corrective maintenance), to respond to new or revised requirements (perfective maintenance), or to adapt the software to changes in the operating environment (adaptive maintenance). Software modifications shall be approved by authorized personnel, documented, verified, validated, and controlled.	√			NP 19-1 Section 2.3.7	
B. In-Use Tests 1. Test problems shall be run whenever the software is installed on a different computer or when significant hardware or system software configuration changes are made. These tests shall be documented, performed by an individual technically competent in the subject area(s), and serve as the basis for determining if the software still meets specified requirements.	√			NP 19-1 Section 2.3.7.2	
2. Periodic in-use manual or automatic self-check routines shall be prescribed and performed for that software for which computer failure or electronic drift can affect required outcomes.	√			NP 20-1 Appendix A	Self check routines are only identified for DAS used on experimental activities.
6.5.2.7 Retirement Phase Criteria shall be developed to determine when software can be retired from use. Methods shall be developed to prevent the use of software that is no longer controlled. Upon retirement user support for a software product is terminated.	√			NP 19-1 Sections 2.3.7.4 and 2.3.8	
 6.6 SOFTWARE VERIFICATION AND VALIDATION 6.6.1 General Requirements A. Verification and validation of software shall include the review of software activities, documentation, and tests to ensure that the software 1. Adequately and correctly performs all intended functions 2. Does not perform any unintended function that either by itself or in combination with other functions can degrade the intended outcomes of the software 	√			NP 19-1 Sections 2.3.2 And 2.3.5 Appendices D and H	
 B. Verification and validation shall be performed by any competent individual(s) or group(s) other than those who performed the software design. The individuals may be from the same organization and may include the designer's supervisor, provided the supervisor 1. Did not specify a singular design approach 2. Did not rule out certain design considerations 3. Did not establish the design inputs used 4. Is the only individual in the organization competent to perform the verification or validation 			√		NWMP Glossary under "Technical Review" requires the reviewer to be fully independent.

QAPD (REV 3) REQUIREMENTS	QAPD (REV 3) REQUIREMENTS APPLICABLE REQUIREMENTS IDENTIFIED		ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
6.6.2 Additional Requirements 6.6.2.1 Verification					
Verification is a formal checking activity performed throughout the evolution of the software life cycle. Verification activities shall be clearly documented, including the identification of those performing and approving the verification. The reviewed documents shall be updated and placed under configuration control. Documentation of review comments and their disposition shall be retained. Comments and their disposition not incorporated shall also be retained in accordance with established procedures.	√			NP 19-1 Section 2.3	
6.6.2.2 Requirements				NID 40 4	
Verification review(s) of software requirements shall ensure that the requirements are complete, verifiable through testing, consistent, and technically feasible as described in section 6.5.2.1.	√			NP 19-1 Appendix C	
6.6.2.3 Design					
Verification review(s) of software design shall evaluate the technical adequacy of the design approach and ensure that all the requirements have been addressed and that the design is complete, verifiable (through testing, using approved test plans and test cases), consistent, technically feasible, and traceable to the software requirements as described in section 6.5.2.2.	√			NP 19-1 Appendix E	
6.6.2.4 Implementation					
Verification of the implementation of software design shall consist of the examination of software logic and source code to ensure adherence to standards and conventions and to ensure that the design has been implemented as described in section 6.5.2.3.	√			NP 19-1 Appendix F	
6.6.2.5 Testing					
Verification of software testing shall consist of reviews to ensure that the specified test criteria, the expected results, and the software development documentation have been met as described in section 6.5.2.4.	√			NP 19-1 Appendices D and H	
6.6.2.6 Installation and Checkout					
Verification of installation and checkout activities consists of reviews to ensure that the software baseline has been established.	√			NP 19-1 Appendix I	
6.6.3 Validation					
A. Software validation is primarily a formal testing activity that shall be performed prior to installation and checkout. It shall be used to demonstrate that the computational model embodied in the software is an acceptable representation of the process or system for which it is intended and that the software produces correct solutions within defined limits for each parameter employed.	√			NP 19-1 Appendix H	

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		REQUIREMENTS		REQUIREMENTS IMPLEME		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A	2000 <u>2</u> 0					
B. Validation methods, test data, software-generated results, and conclusions shall be documented in a form that can be understood by an independent individual technically competent to use the software for the particular problem under study. The documentation shall be reviewed to assess the adequacy and correctness of the documentation in meeting the requirements of this section of the QAPD and the overall acceptability of the software for the intended use.	V			NP 19-1 Appendix H					
C. When the adequacy of the conceptual, mathematical, or computational models or the suitability of procedures and methods cannot be established through testing, alternate calculations, or reference to previously established standards and practices, a documented peer review shall be performed to meet the software validation requirements.	√			NP 19-1 Appendix D					
D. The validation of software modifications shall be subject to selective regression testing to	√			NP 19-1 Section 2.3.7.2					
Detect errors introduced during the modification of the systems or system components									
Verify that the modifications have not caused unintended adverse effects									
Verify that the modified system(s) or system component(s) still meets specified requirements									
6.7 SOFTWARE CONFIGURATION MANAGEMENT									
6.7.1 General Requirements									
Implementation of baseline and change control processes are fundamental to configuration management. A baseline is a collection of all approved components of the software development cycle. As each component is approved it is added to the overall software baseline. A software baseline serves as the basis for further development and maintenance that can be changed only through the use of formal change control procedures. Change control is the process by which a change to a baseline is proposed, evaluated, and approved or rejected.	√			NP 19-1 Section 2.3.7.4					
Software configuration controls shall be planned, including the identification of organizational positions that are authorized to make changes and the methods, procedures, and instructions to be used to control the identification of, access to, changes to, and the status of computer software. Configuration control documents shall indicate how changes will be validated, including regression testing, and how the tests will be documented. These planning documents shall be formally reviewed, approved, and in place before the release of the software for use.	√			NP 19-1 Section 2.3.7 Appendix J, D					

QAPD (REV 3) REQUIREMENTS	REC	APPLICABLE REQUIREMENTS IDENTIFIED		IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
6.7.2 Additional Requirements					
6.7.2.1 Configuration Identification					
Software shall be placed under configuration control as each configuration item is approved. A software baseline shall define the most recent approved software configuration. The configuration items and their associated documentation shall be traceable to one another. A labeling system for configuration items shall be implemented that	√			NP 19-1 Section 2.3.7	
A. Uniquely identifies each configuration item					
B. Identifies changes to configuration items by revision or version identifier	√			NP 19-1 Section 2.3	
C. Provides the ability to uniquely identify each approved configuration of the revised software that is available for use					
6.7.2.2 Configuration Change Control					
A. Changes to software shall be systematically proposed, evaluated, documented, and approved to ensure that the impact and rationale for making the change is carefully assessed prior to updating the software baseline. Changes to previously accepted software shall be subject to the same level of control as the original software.	√			NP 19-1 Section 2.3.7	
B. Information concerning approved changes shall be transmitted to all affected organizations. All changes shall be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes. Only authorized changes shall be made to software baselines. Software verification activities shall be performed for the change as necessary to ensure that the change is appropriately reflected in the software documentation and to ensure that traceability is maintained. The degree of software validation shall be commensurate with the nature and scope of the change.	✓			NP 19-1 Section 2.3.7 Appendix J	
6.7.2.3 Configuration Status Accounting Information shall be maintained that reflects the current status of the software baseline. This includes the identity and version of the approved configuration and the status of any proposed and approved changes to the baseline components. This information shall be available to all designated users of the software upon request.	√			NP 19-1 Section 2.3.7.4	

QAPD (REV 3) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED		ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
6.8 DOCUMENTATION 6.8.1 General Requirements					
Software shall be described in one or more documents that detail user instructions, technical bases, functional requirements, and maintenance-related information sufficient to allow independent verification and maintenance and to provide traceability of the documentation to the software. The documentation shall be reviewed by an individual competent in the technical subject area for which the use of the software is intended. The review shall verify that the documentation adequately and accurately reflects the software that constitute the system and is sufficient to objectively demonstrate that the software requirements have been successfully implemented. Appropriate documentation shall be made available to all designated users of the software.	√			NP 19-1 Section 2.3	
6.8.2 Additional Requirements 6.8.2.1 Procurement Documentation				NP 4-1 Section 2.1.3	
The applicable quality assurance requirements shall be specified and the required vendor-supplied software documentation, plans, and procedures shall be identified in the software procurement documentation.	√			Section 2.1.3	
6.8.2.2 Requirements Documentation					
A. Software requirements documentation shall outline the requirements that the proposed software must satisfy. The software requirements shall, as applicable, address the following: 1. Functionality – the functions the software	√			NP 19-1 Section 2.3 Appendix C	
performs					
Performance - the time-related issues of software operation such as speed, recovery time, response time, etc.					
Constraints - those imposed on implementation activities; any elements that will restrict design options					
Attributes - non-time-related issues of software operation such as portability, acceptance criteria, access control, maintainability, etc.					
External interfaces - interactions with people, hardware, and other software					
B. Software requirements shall be traceable throughout the software development cycle.	√			NP 19-1 Section 2.3	
6.8.2.3 Design and Implementation Documentation				ND 40.4	
Software design and implementation documentation consists of a document or series of documents that	√			NP 19-1 Sections 2.3.2 and 2.3.4	

QAPD (REV 3) REQUIREMENTS	QAPD (REV 3) REQUIREMENTS APPLICABLE REQUIREMENTS IDENTIFIED		ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A	BOOMENTO	
Describe the major components of the software design as they relate to the software requirements	√			NP 19-1 Appendices E, F, and G	
Describe the theoretical basis, embodied mathematical model, control flow, control logic, and data structure(s) of the software					
Describe the allowable or prescribed ranges for inputs and outputs					
 Describe the design in a manner that can be translated into executable code. 					
6.8.2.4 Verification and Validation Documentation					
A. Software verification and validation documentation shall consist of associated plans and shall describe the activities (including the results of reviews and tests) and the criteria for accomplishing the verification of the software throughout the software evolution process. The documentation shall also specify the hardware and software configurations pertinent to the software verification and validation.	√			NP 19-1 Sections 2.3.2 and 2.3.5 Appendices D and H	
B. Software verification and validation documentation shall be organized in a manner that allows traceability from the software requirements to both the software design and to the validated capabilities of the software.					
6.8.2.5 Change Documentation					
Changes to software shall be formally documented. This documentation shall contain a description of the change, the rationale for the change, and the identification of affected configuration items of the software baseline.	√			NP 19-1 Appendix J	
6.8.2.6 User Documentation User documentation should be sufficient to allow any qualified user (i.e., one having adequate technical background) to "set up" and run the software and properly respond to errors. User documentation, at a minimum, shall include	√			NP 19-1 Section 2.3.4 Appendix G	QAPD Section 6.8.2.6, see NP 19-1 Section 2.3.4 Appendix G
A. The software name and version identifier					
Statement(s) of functional requirements and system limitations, including hardware					
C. An explanation of the mathematical model(s) and derivation of the numerical methods used in the software design; physical and mathematical assumptions on which the software is based shall be included, along with an explanation of the capabilities and limitations inherent in the software					

QAPD (REV 3) REQUIREMENTS	APPLICABLE REQUIREMENTS IDENTIFIED		ENTS	IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
D. User instructions that describe user interaction with the software, user messages initiated as a result of improper input and how the user can respond, the identification and description of input and output specifications and formats, and input parameters					
E. A description of any required training necessary to use the software					
User information for obtaining operation and maintenance support					
6.8.2.7 Error Documentation					
Documentation of errors detected during the use of the software following installation and checkout shall be maintained. This documentation can be used for process improvement and to prevent recurrence of errors during the development and maintenance of other software. This documentation shall contain the identity of the software, the classification of the error in terms of its significance to the integrity of the software output, and the corrective action(s).	V			NP 19-1 Section 2.3.7.3 Appendix K	
6.9 PROBLEM REPORTING AND CORRECTIVE ACTION					
6.9.1 General Requirements Problems (i.e., errors, faults, failures, etc.) detected in released software shall be promptly reported in accordance with documented procedures. When problems are detected in a software item, work previously performed using versions of the software that contain that problem shall be evaluated to determine the impact on the completed work. The evaluations shall be documented and retained in accordance with records requirements.	√			NP 19-1 Section 2.3.7.3	
A. A system shall be established and maintained to record, classify, analyze, track, and report software problems (in released versions) and the associated corrective actions. Problems shall be promptly reported to any affected organizations and the resolution shall be formally processed.	√			NP 19-1 Appendix K	
B. When problems are discovered in software or software results, the sponsoring organization shall determine the affect on previous use(s) and the need for corrective action based on sufficient information obtained from the affected users. Corrective action shall ensure that	√			NP 19-1 Section 2.3.7.3 Appendix K	

QAPD (REV 3) REQUIREMENTS		PPLICA UIREM ENTIF	IENTS	IMPLEMENTING DOCUMENTS	COMMENTS
	Υ	N	N/A		
Problems are identified, evaluated, documented, and, if required, corrected					
Problems are assessed for their impact on past and present uses of the software					
Changes to software are in accordance with the software configuration management requirements of this section of the QAPD					
Results are provided to the affected users along with any revised software documentation					
C. Problems that could significantly affect decisions based upon prior use or that require significant modification to the software shall be identifiable to all users. Errors that have been determined to represent a condition adverse to quality shall be controlled in	√			NP 19-1 Appendix K NP 16-1	
accordance with section 1.3 of this QAPD.					
6.10 ACCESS CONTROL To the extent appropriate, controls shall be established to permit authorized and prevent unauthorized access to software that has been accepted in accordance with this section.	√			NP 19-1 Sections 2.3.6.2 and 2.3.6.3	

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